6560-50-P

U. S. ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 63

[AD-FRL-5802-8]

RIN-2060-AE83

National Emission Standards for Hazardous Air Pollutants for Source Categories: Pharmaceuticals Production

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: This action promulgates national emission standards for hazardous air pollutants (NESHAP) to reduce air emissions of hazardous air pollutants (HAP) from existing and new facilities that manufacture pharmaceutical products. The Agency intends that this promulgated rule will have a common technology basis with a rule promulgated this date under the Clean Water Act (CWA); this will allow coordinated and cost effective compliance planning by the industry. The standards implement section 112 of the Clean Air Act (CAA) as amended in 1990. The standards apply to major source facilities which produce pharmaceutical products.

The major HAP emitted by facilities covered by this final rule include methylene chloride, methanol, toluene, and hydrogen chloride. Methylene chloride is considered to be a probable human carcinogen and the other pollutants can cause noncancer health effects in humans. The promulgated rule is estimated to reduce HAP emissions from existing

facilities by 22,000 megagrams per year (Mg/yr) (24,000 tons per year [tons/yr]). It also reduces volatile organic compound (VOC) emissions.

DATES: This regulation is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Office of the Federal Register as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See the SUPPLEMENTARY INFORMATION section concerning judicial review.

ADDRESSES: Docket. Docket No. A-96-03, containing supporting information used in developing the standards, is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at EPA's Air Docket Section, Waterside Mall, Room 1500, 1st Floor, 401 M Street SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information concerning the final CAA standard, contact Mr. Randy McDonald at (919) 541-5402, Organic Chemicals Group, Emission Standards Division (MD-13), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For further information concerning the CWA effluent limitation guidelines pretreatment standards and new source performance standards, contact Dr. Frank H. Hund, at (202) 260-7786,

Engineering and Analysis Division (4303), U. S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460. For information concerning applicability and rule determinations, contact your State or local representative or the appropriate EPA regional representatives. For a listing of EPA regional contacts, see the following "SUPPLEMENTARY INFORMATION" section.

SUPPLEMENTARY INFORMATION: An electronic version of documents from the Office of Air and Radiation (OAR) are available through EPA's OAR Technology Transfer Network Web site (TTNWeb). The TTNWeb is a collection of related Web sites containing information about many areas of air pollution science, technology, regulation, measurement, and prevention. The TTNWeb is directly accessible from the Internet via the World Wide Web at the following address, "http://www.epa.gov/ttn". Electronic versions of this preamble and rule are located under the OAR Policy and Guidance Information Web site, "http://www.epa.gov/ttn/oarpg/", under the Federal Register Notices section. If more information on the TTNWeb is needed, contact the Systems Operator at (919) 541-5384.

Regulated entities. Entities potentially regulated are those which produce pharmaceutical products and intermediates and are located at facilities that are major

sources as defined in section 112 of the CAA. Regulated categories and entities include:

Category	Regulated entities
Industry	• Facilities described by the SIC codes 2833 and 2834 and NAICS codes 32541 and 325412.
	• Producers of finished dosage forms of drugs, for example, tablets, capsules, solutions, that contain an active ingredient generally, but not necessarily, in association with inactive ingredients
	• Producers of components whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility, company, business, organization, etc., is regulated by this action, you should carefully examine the applicability criteria in § 63.1250 of the rule. If you have questions regarding the applicability of this action to a particular entity, contact the appropriate Regional representative:

Region I:
NESHAP (MACT) Coordinator
U. S. EPA Region I
John F. Kennedy Federal Building
One Congress Street
Boston, MA 02203-001
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Region II:
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U. S. EPA Region II
290 Broadway Street
New York, NY 10007-1866
(212) 637-4023 (Umesh)
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Region III:
Bernard Turlinski
U. S. EPA Region III
841 Chestnut Building
Philadelphia, PA 19107
(215) 566-2150

Region IV:
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U. S. EPA Region IV
Atlanta Federal Center
61 Forsyth Street SW
Atlanta, GA 30303-3104
(404) 562-9131

Region V:
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77 West Jackson Boulevard
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Region VII:
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Denver, CO 80202-2466
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Region IX:
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San Francisco, CA 94105
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Seattle, WA 98101
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Judicial review. Under section 307(b)(1) of the Act, judicial review of NESHAP is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this final rule. Under section 307(b)(2) of the Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements. The information presented in this preamble is organized as follows:

I. List of Source Categories

I. List of Source Categories

Section 112 of the amended Act requires that EPA evaluate and control emissions of HAP. The control of HAP is achieved through promulgation of emission standards under sections 112(d) and 112(f) and work practice and equipment standards under section 112(h) for categories of sources that emit HAP. On July 16, 1992, EPA published an initial list of major and area source categories to be regulated (57 FR 31576). Included on that list were major sources emitting HAP from pharmaceuticals production.

Production methods used in the manufacture of pharmaceutical products include both batch and continuous operations, although batch operations make up a majority of the processes. The sizes of the facilities range from those that make one product at the rate of several hundred kilograms per year (kg/yr) to those that produce numerous

pharmaceutical products on the scale of thousands of kilograms (megagrams [Mg]) per year. Air emissions of HAP compounds originate from breathing and withdrawal losses from storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams. Pollutants emitted from the production processes include a range of organic compounds, including VOC and several specific HAP. Among the most prevalent are methylene chloride and methanol, which account for nearly 70 percent of all HAP emissions from this industry. Detailed information describing manufacturing processes and emissions can be found in the basis and purpose document located in Docket A-96-03, Item No. III-B-01.

As of 1992, over 80 U.S. companies at 270 facilities were producing pharmaceutical products. Manufacturing operations covered by this NESHAP include chemical synthesis, formulation, fermentation, and extraction processes and are generally classified under standard industrial classification 283. An estimated 101 facilities are considered to be major sources according to the CAA criterion of having the potential to emit 10 tons/yr of any one HAP or 25 tons/yr of combined HAP, based on 1992 emissions data. Today’s final standard applies to all major

sources that produce pharmaceutical products. Area sources are not subject to this standard.

II. Background

A. Summary of Considerations Made in Developing These Standards

This regulation reduces emissions of many of the HAP listed in section 112(b)(1) of the CAAA. The alternatives considered in the development of this regulation, including those alternatives selected as standards for new and existing sources, are based on process and emissions data received from the existing facilities known by the EPA to be in operation.

Regulatory alternatives more stringent than the maximum achievable control technology (MACT) floor (minimum control level) were selected when they were judged to be reasonable, considering cost, nonair impacts, and energy requirements.

Today's final rule gives existing affected sources 3 years from the date of promulgation to comply. This is the maximum amount of time allowed by the Act. New affected sources are required to comply with the standard upon startup.

Included in today's final rule are methods for determining initial compliance as well as monitoring, recordkeeping, and reporting requirements. All of these components are necessary to ensure that affected sources

comply with the standards both initially and over time. However, the EPA has made every effort to simplify the requirements in the final rule. In addition, EPA has significantly reduced the amount of cross-referencing to other rules included in today's final standards at the request of facilities affected by these standards.

In addition, this rule contains an important and innovative pollution prevention alternative for the pharmaceutical industry that provides an option to reduce HAP emissions through reductions in HAP solvent consumption as opposed to installing end-of-pipe controls. The EPA has developed a regulation that provides a pollution prevention compliance alternative to the traditional control requirements, and the EPA encourages the pharmaceutical industry to meet the CAA requirements through its use. This alternative demonstrates EPA's commitment to developing regulations that are cost effective and flexible, and that reduce monitoring, recordkeeping, and reporting burdens.

Representatives from other interested EPA offices and programs, including State and regional environmental agency personnel, and representatives from industry participated in the regulatory development process as MACT partnership members. For example, Region II, acting as the lead, worked closely with the States of New York and New Jersey as well as the pharmaceutical industry in developing the pollution

prevention alternative. The partnership members were given opportunities to review and comment on the regulation prior to proposal and had the opportunity to comment on the proposed standards and to provide additional information during the public comment period that followed proposal.

The standards were proposed in the Federal Register on April 2, 1997 [62 FR 15754]. The preamble to the proposed standards and the basis and purpose document (Docket Item III-B-01) described the rationale for the proposed standards. Public comments were solicited at the time of proposal. To provide interested persons the opportunity for oral presentation of data, views, or arguments concerning the proposed standards, a public hearing was offered at proposal. However, the public did not request a hearing and, therefore, one was not held. The public comment period was from April 2, 1997 to July 2, 1997. More than 40 letters were received during the comment period. Commenters included industry representatives and State agencies. The comments were carefully considered, and changes were made in the proposed standards when determined by the EPA to be appropriate. A detailed discussion of these comments and responses can be found in the promulgation background information document (BID) which is located in Docket No. A-96-03, Item V-B-01, which is referenced in the ADDRESSES section of this preamble. The promulgation

BID (summary of comments and responses document) serves as the basis for the revisions that have been made to the standards between proposal and promulgation. Section VI of this preamble discusses these major changes.

B. Regulatory Background

Today's final rule implements section 112(d) of the Clean Air Act (CAA) amendments of 1990, which require the Administrator to regulate emissions of HAP listed in section 112(b) of the CAA. The intent of this rule is to protect the public health by requiring new and existing major sources to reduce generation of emissions by using pollution prevention strategies or to control emissions to the level achievable by the maximum achievable control technology (MACT), taking into consideration the cost of achieving such emission reductions, any nonair quality and other air quality related health and environmental impacts, and energy requirements.

In 1978, EPA published a control techniques document entitled "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," EPA-450/2-78-029. The control technique guidelines document (CTG) contains a presumptive norm for reasonably available control technology (RACT) for the manufacturing operations covered under SIC Codes 2833 and 2834. Today's final rule does not affect the presumptive RACT guidelines, although a

portion of emissions sources are covered by both today's final regulation and the CTG document.

In 1994, EPA promulgated National Emission Standards for Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks. Pharmaceutical processes, defined as processes that synthesize pharmaceutical intermediates or final products using carbon tetrachloride or methylene chloride as a reactant or process solvent, are subject to this rule. Today's final rule requires control of leaking components that are currently not subject to the Negotiated Regulation for Equipment Leaks, but that contain and/or transport HAP and are associated with processes in this source category. Today's rule also allows sources subject to the Negotiated Regulation to comply with the LDAR provisions of this rule.

C. Regulation of the Pharmaceutical Manufacturing Industry Under the Clean Water Act

The Clean Water Act (CWA) and a recent settlement agreement (see 59 FR 25869) require EPA to develop effluent limitations guidelines and standards regulations for the pharmaceutical manufacturing industry.

On May 2, 1995 at 60 FR 21592, the EPA proposed best available technology (BAT) economically achievable and new source performance standards (NSPS) regulations for 53 volatile and semivolatile organic pollutants of which

17 are HAP. The Agency also proposed pretreatment standards for existing sources (PSES) and performance standards for new sources (PSNS) for 45 volatile organic pollutants of which 16 are HAP. The technology basis for the volatile organic limitations were based on steam stripping and advanced biological treatment. The proposed NSPS and PSNS differed from BAT and PSES, respectively, in that they were based on steam stripping plus distillation.

In the April 2, 1997 proposal EPA indicated that it was considering changing the BAT technology basis to advanced biological treatment only. The EPA also described three options under consideration for setting PSES and PSNS to address HAP and non-HAP wastewater pollutant discharges not controlled by the MACT standards. Under the first option compliance with the MACT standards would constitute compliance with PSES and PSNS. Option 2 involved compliance with the MACT standards plus additional PSES based on the performance data base for the 1995 proposed PSES for all volatile organic pollutants except alcohols and related pollutants, and Option 3 was the same as Option 2 except the additional pollutants included alcohols and related pollutants.

On August 8, 1997, at 62 FR 42720, the EPA published a Notice of Availability (NOA) to allow public comment on the data received since the May 2, 1995 CWA proposal and to

further develop and revise options for the control of volatile organic pollutant discharges presented in the April 2, 1997 MACT proposal. The EPA provided the results of an EPA sampling study designed to provide information concerning the pass-through analysis for water soluble organic pollutants such as methanol and provided a discussion thereafter of the final pass-through analysis that EPA would be performing with respect to these and other pollutants. The EPA also presented revisions to the pretreatment options (Options 2 and 3) which were first suggested in the CWA section of the April 2, 1997 MACT proposal.

Elsewhere in today's Federal Register EPA is publishing final effluent limitation guideline and standards under the Clean Water Act for the pharmaceutical manufacturing point source category.

III. Authority for National Emission Standards for Hazardous Air Pollutants (NESHAP) Decision Process

A. Source of Authority for NESHAP Development

Section 112 of the Clean Air Act gives the EPA the authority to establish national standards to reduce air emissions from sources that emit one or more HAP. Section 112(b) contains a list of HAP to be regulated by NESHAP. Section 112(c) directs the Agency to use this pollutant list to develop and publish a list of source

categories for which NESHAP will be developed; this list was published in the Federal Register on July 16, 1992 (57 FR 31576). The Agency must list all known categories and subcategories of "major sources" that emit one or more of the listed HAP. A major source is defined in section 112(a) as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit in the aggregate, considering controls, 10 tons/yr or more of any one HAP or 25 tons/yr or more of any combination of HAP.

B. Criteria for Development of NESHAP

The NESHAP are to be developed to control HAP emissions from both new and existing sources according to the statutory directives set out in section 112(d) of the Act. The statute requires the standards to reflect the maximum degree of reduction in emissions of HAP that is achievable for new or existing sources. This control level is referred to as the "maximum achievable control technology" (MACT). The selection of MACT must reflect consideration of the cost of achieving the emission reduction, any nonair quality health and environmental impacts, and energy requirements for control levels more stringent than the floor (described below).

The MACT floor is the least stringent level for MACT standards. For new sources, the standards for a source category or subcategory "shall not be less stringent than the emission control that is achieved in practice by the best controlled similar source, as determined by the Administrator" [section 112(d)(3)]. Existing source standards should be no less stringent than the average emission limitation achieved by the best performing 12 percent of the existing sources for categories and subcategories with 30 or more sources or the average emission limitation achieved by the best performing 5 sources for categories or subcategories with fewer than 30 sources [section 112(d)(3)]. The determination of the MACT floor for existing sources under today's rule is that the average emission limitation achieved by the best performing sources is based on a measure of central tendency, such as the arithmetic mean, median, or mode. The determination of percentage reduction in the production-indexed consumption factors used in the pollution prevention alternative is based on the criteria that the alternative must achieve emissions reductions equivalent to what would have been achieved by complying with the MACT.

IV. Summary of Promulgated Standards

A. Source Categories to be Regulated

Today's final rule regulates HAP emissions from pharmaceutical production facilities that are determined to be major sources. These standards apply to existing sources as well as new sources. The final standards for existing and new source are summarized in Table 1.

TABLE 1. STANDARDS FOR NEW AND EXISTING SOURCES

Emission point	New or existing?	Applicability		Requirement
		Applicability level	Cutoff	
Process vents	New	Processes	>400 lb HAP/yr uncontrolled	98 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit
	Existing	Processes	≥2,000 lb HAP/yr controlled	93 percent control or 2,000 lb HAP/yr or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit (if there are any vents in a process not manifolded to the control device, process must still meet 93 percent control); and 98 percent* for individual vents (within a process) meeting cutoff based on flow and emissions or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit
Storage tanks	New and existing	≥10,000 gal and <20,000 gal	≥1.9 psia vapor pressure of liquid stored	90 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit
		≥20,000 gal	≥1.9 psia vapor pressure of liquid stored	95 percent control or 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet limit**
Wastewater	New and existing	>1 Mg/yr total HAP load from all POD from PMPU	≥1,300 ppm at POD of Table 2 HAP	99 percent reduction of Table 2 HAP
			≥5,200 ppmw at POD of total HAP load	99 percent reduction of Table 2 HAP 90 percent reduction of Table 3 HAP 95 percent reduction of total HAP using biotreatment
		>1 Mg/yr total HAP load from facility	≥10,000 ppmw at POD of total HAP load	99 percent reduction of Table 2 HAP 90 percent reduction of Table 3 HAP 95 percent reduction of total HAP using biotreatment
	New	>1 Mg/yr total HAP load from all POD from PMPU	≥110,000 ppmw at POD of Table 3 HAP	99 percent reduction of Table 3 HAP and existing source requirements
Equipment leaks	New and existing	All components in HAP service		LDAR program

*For process vents controlled to 93 percent prior to April 2, 1997, no additional control is required.
**For tanks controlled to 90 percent prior to April 2, 1997, no additional control is required.

B. Pollutants to be Regulated and Associated Environmental and Health Benefits

Pharmaceutical production facilities emit an estimated 34,000 Mg/yr of organic and inorganic HAP. Organic HAP include methylene chloride, methanol, toluene, dimethylformamide, and hexane as well as other HAP. Hydrogen chloride is an inorganic HAP emitted by this industry. Today's final rule reduces HAP emissions from pharmaceutical facilities by 65 percent. Some of these pollutants are considered to be carcinogenic, and all can cause toxic health effects following exposure, including nausea, headaches, and possible reproductive effects. The EPA does recognize that the degree of adverse effects to human health can range from mild to severe. The extent and degree to which the human health effects may be experienced is dependent upon (1) the ambient concentration observed in the area (e.g., as influenced by emission rates, meteoro-logical conditions, and terrain); (2) the frequency of and duration of exposures; (3) characteristics of exposed individuals (e.g., genetics, age, pre-existing health conditions, and lifestyle) which vary significantly with the population; and (4) pollutant specific characteristics (toxicity, half-life in the environment, bioaccumulation, and persistence).

Most of the organic HAP emitted from this industry are classified as VOC. The emission controls for HAP will reduce non-HAP VOC emissions as well. Emissions of VOC have been associated with a variety of health and welfare impacts. Volatile organic compound emissions, together with nitrogen oxides, are precursors to the formation of tropospheric ozone. Exposure to ambient ozone is responsible for a series of public health impacts, such as alterations in lung capacity; eye, nose, and throat irritation; nausea; and aggravation of existing respiratory disease. The welfare impacts from exposure to ambient ozone include damage to selected commercial timber species and economic losses for commercially valuable crops such as soybeans and cotton.

Hydrogen chloride is listed under section 112(r) of the CAA. The intent of section 112(r), Prevention of Accidental Releases, is to focus on chemicals that would pose a significant hazard to the community in the event of an accident, to prevent their accidental release, and to minimize consequences should a release occur. Hydrogen chloride, along with the other substances listed under section 112(r)(3), is listed because it is known to cause, or may be reasonably anticipated to cause death, injury, or serious adverse effects to human health or the environment (see 59 FR 4478, January 31, 1994). Sources that handle

hydrogen chloride in greater quantities than the established threshold quantity under section 112(r)(5) are subject to the risk management program requirements under section 112(r)(7) (see 58 FR 54190, October 20, 1993).

In essence, the MACT standards mandated by the CAA will ensure that all major sources of air toxic emissions achieve the level of control already being achieved by the better controlled and lower emitting sources in each category. This approach provides assurance to citizens that each major source of toxic air pollution will be required to effectively control its emissions. In addition, the emission reductions achieved by today's final standards, when combined with the reductions achieved by other MACT standards, will contribute to achieving the primary goal of the CAA, which is to "protect and enhance the quality of the Nations's air resources so as to promote the public health and welfare and the productive capacity of its population" (the CAA, section 101(b)(1)).

C. Affected Sources

Emission points identified from pharmaceuticals production include process vents, equipment leaks, storage tanks, wastewater collection and treatment systems, and heat exchange systems. The affected source subject to this subpart is any pharmaceutical manufacturing operation, as defined in § 63.1251 of today's final rule, that meets the

following criteria: (1) it manufactures a pharmaceutical product, as defined in § 63.1251; (2) it is located at a plant site that is a major source as defined in section 112(a) of the Act; and (3) it processes, uses, or produces HAP. Based on this definition of affected source, new sources are created by reconstructing existing sources, constructing new “greenfield” facilities, or constructing an addition to an existing source which is a dedicated pharmaceutical manufacturing process unit (PMPU) and exceeds 10 tons/yr of an individual HAP or 25 tons/yr of combined HAP. Reconfigurations of existing equipment do not constitute “construction” and therefore NSM would not be triggered under this circumstance. Therefore, a new affected source subject to this subpart is any affected source for which construction or reconstruction commenced after April 2, 1997, and the standard was applicable at the time of construction or reconstruction, or any PMPU that is dedicated to manufacturing a single product that has the potential to emit 10 tons per year of any one HAP or 25 tons per year of combined HAP, for which construction commenced after April 2, 1997.

The PMPU is defined according to the equipment used to make a pharmaceutical product. The PMPU also includes storage tanks that are associated with the process.

D. Storage Tank Provisions

Today's final standards require existing and new sources to control emissions from storage tanks having volumes greater than or equal to 38 cubic meters (m^3) (10,000 gallons), and storing material with a vapor pressure of greater than or equal to 13.1 kPa (1.9 psi). The final standards require that emissions from storage tanks with capacities greater than or equal to 38 m^3 (10,000 gallons) and less than 75 m^3 (20,000 gallons) be reduced by 90 percent. Emissions from storage tanks greater than or equal to 75 m^3 (20,000 gallons) must be reduced by 95 percent. One of the following control systems can be applied to meet these requirements:

1. An internal floating roof with specified seals and fittings;

2. An external floating roof with specified seals and fittings;

3. An external floating roof converted to an internal floating roof with specified seals and fittings; or

4. A closed vent system with the appropriate 90 or 95 percent efficient control device.

The final rule also includes an alternative standard for any storage tank vents that are routed to an add-on control device. Under the alternative standard, an owner or operator may choose to comply with a total organic compound

(TOC) and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution and at the outlet of the control device. The alternative standard is discussed in more detail in sections IV.K and VI.G of this preamble and is included in § 63.1253(d) of the final rule. Today's final rule does not provide for vapor balancing systems to be used as an alternative means of control for storage tanks.

E. Process Vent Provisions

The MACT standard for most existing process vents was set at the floor level of control, which was determined to be 93 percent control. The final standards require existing sources to reduce emissions from the sum of all vents within a process to 900 kg/yr (2,000 pounds per year [lb/yr]), considering control, or meet an overall process control level of 93 percent. The 2,000 lb/yr compliance option is limited to seven processes per year per facility. Additionally, a regulatory alternative beyond the floor was selected that requires 98 percent control of some large emission vents. Individual process vents (manifolded or nonmanifolded) meeting the annual emissions and flow rate criteria are required to achieve 98 percent control, independent of the overall 93 percent requirement. (Those process vents achieving 93 percent control prior to April 2,

1997 are not required to meet the 98 percent control requirement.)

The MACT standard for process vents at new sources was set at the floor level of control. The MACT floor was determined from the best controlled similar source and is based on the most stringent control level achieved for both chemical synthesis and formulation type processes. Today's final standards for new sources require 98 percent control of vents in a process that has uncontrolled emissions greater than 182 kg/yr (400 lb/yr).

An alternative standard for process vents was added to the final rule [see § 63.1254(c)]. Under the alternative standard, an owner or operator may choose to comply with a TOC and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution and at the outlet of the control device. If only a portion of the process vents associated with a process comply with the alternative standard, then the remaining process vents must be controlled to the levels required by the standards (e.g., 93 percent for the sum of remaining vents and/or 98 percent control of some individual vents for existing sources and 98 percent control of the sum of remaining vents for new sources).

The process vent and storage tank standards also contain provisions for complying in essentially the same

manner as is described by the alternative standard--by routing streams to control devices achieving an outlet concentration of TOC and hydrogen halide and halogen limit of 20 ppmv or less, measured prior to dilution. These provisions differ from those described under the Alternative standard only in the monitoring options available.

F. Wastewater Provisions

The MACT floor for wastewater at existing sources was determined to be 54 percent control of HAP emissions from wastewater. The EPA calculated HAP concentration cutoffs for wastewater streams, above which steam stripping of wastewater streams would result in a level of control as stringent as the floor. This approach is similar to the hazardous organic NESHAP (HON) and allows for the control of those wastewater streams containing the most significant amount of HAP. The final standards require existing sources to control wastewater with the following characteristics at the point of determination (POD):

1. Streams having partially soluble HAP compound concentrations of 1,300 ppmw or greater and a total PMPU HAP load of 1 Mg/yr or greater;

2. Streams having a combined total HAP concentration of 5,200 ppmw or greater and a total PMPU load of 1 Mg/yr or greater;

3. Streams having a total HAP concentration of 10,000 ppmw with a total facility HAP load of 1 Mg/yr or greater; or

The final standards require that air emissions from wastewater collection systems be suppressed and that wastewater is treated. Compliance is demonstrated by one of the following methods:

1. Using an enhanced biotreatment system for soluble HAP;

2. Demonstrating removals achieving 99 percent by weight of partially soluble HAP compounds, and 90 percent by weight of soluble HAP compounds, from treatment systems; or

3. Demonstrating a removal of 95 percent by weight of total organic HAP from treatment systems.

For new sources, the MACT floor for wastewater is based on a facility that currently incinerates a significant percentage of wastewater containing HAP in an incinerator combusting a mixture of wastes. The final standards require the same applicability and control requirements described above for existing sources and an increased removal of solubles (from 90 to 99 percent) for streams having a soluble HAP concentration of 110,000 ppmw at any of the load criteria (1 Mg/yr total HAP from the PMPU, or facility).

A de minimis HAP concentration and flow rate exemption was added to today’s final rule. Streams containing less

than 5 ppmw of partially soluble and/or soluble HAP and a total yearly load of 0.05 kg/yr of partially soluble and/or soluble HAP are not considered wastewater, and thus, are exempted from the wastewater provisions in today's final rule.

G. Equipment Leaks

Today's final rule contains revisions to the proposed equipment leak requirements that were originally based on subpart H (of the HON rule). The final rule primarily contains changes to the standards for valves and connectors in gas/vapor service and light liquid service. The standards for valves in gas/vapor service and in light liquid service in section GGGA-6 were changed as follows: the requirement to implement a quality improvement program and all references to § 63.175 have been removed; an allowance for monitoring every 2 years for those processes with less than 0.25 percent leaking valves has been added; an allowance for valve subgrouping was also added; the equation used to determine the percent of leaking valves in a process was changed to eliminate the optional credit for valves removed, Vc; and the rolling average of leaking valves was revised so that it is calculated as an average of the last 3 monitoring periods for annual or biannual monitoring programs. The monitoring schedule for connectors in gas/vapor service and light liquid service in

section GGGA-3(a)(7) also was revised to allow for decreased monitoring for those components with the lowest leak rates. For leak rates less than 0.25, the monitoring frequency for connectors is now once every 8 years.

H. Pollution Prevention Alternative

Today's final standards include a pollution prevention (P2) alternative standard that meets the MACT floor for existing sources and can be implemented in lieu of meeting the requirements for existing process vents, storage tanks, wastewater streams and equipment leaks. The P2 alternative only applies to existing sources and includes two options which are shown in Table 2. Under option 1, owners or operators can satisfy the requirements for all emission source types associated with each pharmaceutical manufacturing process unit (PMPU) by demonstrating that the production-indexed consumption of HAP has decreased by at least 75 percent from a baseline set no earlier than the 1987 calendar year. The production indexed HAP consumption factor is expressed as kg HAP consumed/kg product produced. Under the second P2 option, owners or operators must demonstrate at least a 50 percent reduction in the production indexed HAP consumption factor, plus an additional amount of reduction in HAP emissions through the use of add-on controls, such that the overall reduction in HAP emissions is at least 75 percent from the baseline period.

TABLE 2. ALTERNATIVE P2 STANDARD

Option	Description of P2 option
1	Demonstrate at least a 75 percent reduction in the kg consumption/kg production factor from a baseline period.
2	Demonstrate at least a 50 percent reduction in the kg/kg factor, plus an additional reduction from add-on control equivalent to at least a 75 percent overall reduction in the kg/kg factor from baseline.

The following restrictions also apply to the pollution prevention standards in today's final rule. For any reduction in the production-indexed HAP consumption factor that is achieved by reducing a HAP that is also a VOC, an equivalent reduction in the production-indexed VOC consumption factor is required. For any reduction in the production-indexed HAP consumption factor that is achieved by reducing a HAP that is not a VOC, the production-indexed VOC consumption factor may not be increased. Also, the final rule allows owners or operators of PMPU's that generate HAP emissions to qualify for the pollution prevention alternative, provided that the HAP emissions generated in the PMPU are reduced to the required levels for process vents, storage tanks, wastewater streams and equipment leaks specified in §§ 63.1252 through 63.1256 of today's final standards. The baseline production-indexed HAP and VOC consumption factors must be based on consumption and production values averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the

first 3 years of operation (beginning no earlier than 1987), whichever is the lesser time period. Processes that began operation after April 2, 1997 are not eligible for the P2 alternative.

Today's final standards also require owners and operators complying with the P2 standard to submit a P2 Demonstration Summary as part of the Precompliance Notification Report that describes how the P2 alternative will be applied at their facilities. The minimum data requirements for the P2 Demonstration Summary are listed in § 63.1257(f) of today's final rule.

I. Heat Exchange Provisions

Today's final standards for heat exchange systems are unchanged from proposal. Owners or operators must comply with the heat exchange provisions listed in the HON at § 63.104 with two exceptions: (1) the monitoring frequency shall be no less than quarterly, and (2) owners or operators of heat exchange systems that meet current good manufacturing practice (CGMP) requirements at 21 CFR part 211 may elect to use the physical integrity of the reactor as the surrogate indicator of heat exchange system around reactors.

J. Emissions Averaging Provisions

The emissions averaging provisions in today's final rule are unchanged from proposal. The final rule allows emissions averaging among process vents and among storage

tanks at existing sources. Restrictions on the use of emissions averaging are listed in § 63.1252(d) of today's final rule and are essentially the same as those contained in the HON. The alternative standard (see following section K) is not to be included in the emissions averaging provisions and/or calculations.

K. Alternative Standard

For owners or operators of affected sources that treat emissions with an add-on control device, an alternative standard has been added under §§ 63.1253(d) (storage tanks) and 63.1254(c) (process vents). To comply with today's alternative standard(s), the control device must achieve an outlet, undiluted TOC concentration, as calibrated based on methane or the predominant HAP, of 20 ppmv or less and a hydrogen halide and halogen concentration of 20 ppmv or less, as demonstrated through the test methods and procedures in § 63.1257 and monitoring provisions in § 63.1258. The applicability level is the control unit and all sources vented to the control unit which is considered one regulated entity. Because the applicability of this standard is focused on the control device, this scenario is considered one regulated entity with regard to the number of violations that would apply if there is an exceedance of the 20 ppmv TOC and 20 ppmv hydrogen halide and halogen outlet concentration limit(s). The remaining process vents within

a process not controlled by the alternative standard must be controlled to the percent reduction required by the standards.

L. Test Methods and Compliance Procedures

To determine compliance with the percent reduction requirement for pharmaceutical process vents, uncontrolled and controlled emissions from all process vents within the process shall be quantified to demonstrate the appropriate overall reduction requirements (93 percent or 98 percent). For process vents controlled by devices handling less than 10 tons/yr, the owner or operator can either test or use calculational methodologies to determine the uncontrolled and controlled emission rates from individual process vents. For process vents controlled by devices handling more than 10 tons/yr, tests are required to determine the reduction efficiency of each device. Performance test provisions require testing under worst-case conditions, but the final rule provides flexibility in determining these worst-case conditions. Control devices that have previously been tested under conditions required by this standard and condensers are exempt from emissions testing. Testing is not required for devices used to control emission streams from storage or wastewater sources exclusively. However, if testing is conducted, then the same methods apply.

M. Monitoring Requirements

Monitoring is required in the final rule to determine whether a source is in compliance on an ongoing basis. This monitoring is done either by continuously measuring emission reductions directly or by continuously measuring a site-specific operating parameter, the value of which is established by the owner or operator during the initial compliance determination. The operating parameter value is defined as a single point at either a minimum or maximum value established for a control device that, if achieved on a daily average or block average by itself or in combination with one or more other operating parameter values, determines that an owner or operator is complying with the applicable operating limits. These parameters are required to be monitored at 15-minute intervals throughout the operation of the control device for devices controlling greater than 1 tons/yr. For devices controlling streams totaling less than 1 ton/yr, only a site-specific periodic verification that the devices are operating as designed is required to demonstrate continuous compliance. Owners and operators must determine the most appropriate method of verification and propose this method to the Agency for approval in the precompliance report, which is due 6 months prior to the compliance date of the standard. The monitoring requirements apply to all control devices, even

those used exclusively for storage tanks or wastewater sources.

N. Recordkeeping and Reporting Requirements

Table 1 to subpart GGG was revised to clarify the specific requirements of the final rule and the referenced requirements in the General Provisions. A summary column describing the requirements of each part of the General Provisions has been added to Table 1 and additional comments address wording issues and exceptions to the General Provisions language.

V. Summary of Environmental, Energy, Cost, and Economic Impacts

These NESHAP would affect pharmaceutical production facilities that are major sources in themselves, or constitute a portion of a major source. There are 270 existing facilities manufacturing pharmaceuticals, 101 of which were assumed to be major sources for the purpose of developing these standards and calculating impacts. The expected rate of growth for the pharmaceutical industry is expected to be 2.4 percent per year through 1998.

A. Air Impacts

Today’s final standards will reduce HAP emissions from existing sources by 22,000 Mg/yr (24,000 tons/yr) from the baseline level, a reduction of 65 percent from baseline, and

75 percent from uncontrolled. These reductions also will occur if facilities elect to implement the alternative pollution prevention standard. Since many of the HAP emitted by the pharmaceutical industry are also VOC, today's final standards also will reduce VOC emissions.

B. Water and Solid Waste Impacts

Much of the steam stripping operations will result in recoverable material. However, the new source requirement for very rich, soluble HAP-containing wastewater is expected to generate solid waste. The EPA estimates that an average of 900 tons of solid waste per year per facility will be generated as a result of today's final standards. However, biological treatment is a possible means of compliance.

C. Energy Impacts

Today's final standards for the pharmaceuticals source category will require an additional energy usage of $2,400 \times 10^9$ British thermal units per year (Btu/yr).

D. Cost Impacts

The emission reductions required by this regulation can be achieved using one or more of several different techniques. To determine costs, certain control scenarios were assumed. The scenarios used in costing were judged to be the most feasible scenarios possible for meeting the requirements of the standards from a technical and cost standpoint. The total control cost includes the capital

cost to install the control device, the costs involved in operating the control device, and costs associated with monitoring the device to ensure compliance. Monitoring costs include the cost to purchase and operate monitoring devices, as well as reporting and recordkeeping costs required to demonstrate compliance. Nationwide, the total annual cost of this standard to the industry for existing and new sources is approximately $64 million and $11 million, respectively (1998 dollars). To estimate these annual costs, capital costs were annualized over 10 years (with no delay for installation). (The annual costs presented in the preamble to the effluent limitations guidelines and standards are lower than the above costs because they are based on a longer annualization period. Costs for the effluent guidelines limitations and standards are annualized over 16 years (a 1-year installation period plus a 15-year project life). As a result, annual costs for existing sources in the preamble to the effluent limitations guidelines and standards (referred to as pretax annualized costs for the MACT standards rule for all facilities) are reported at $58.4 million.) The EPA believes that monitoring, reporting, and recordkeeping costs will be substantially reduced for those facilities that choose to comply with today’s final rule through either the P2 option

or the alternative standard of 20 ppm TOC and 20 ppm hydrogen halides and halogens.

E. Economic Impacts

The economic impact analysis of this standard shows that the estimated price increase from compliance with the recommended standards for process vents, storage tanks, and wastewater is 1.1 percent. Estimated reduction in market output is 1.9 percent.

No plant closures are expected from compliance with this set of alternatives. For more information, consult the economic impact report entitled “Economic Analysis of Air Pollution Regulation Regulations: Pharmaceutical Industry, August 1996.”

VI. Major Comments and Changes to the Proposed Standards

In response to comments received on the proposed standards, changes have been made to the final standards. While some of these changes are clarifications designed to make EPA’s intent clearer, many of them are significant changes to the requirements of the proposed standards. A summary of the substantive comments and/or changes made since proposal are described in the following sections. Detailed responses to public comments are included in the promulgation BID: Summary of Public Comments and Responses (Docket Item No. V-B-01). Additional information on the

final standards is contained in the docket for this rulemaking (see ADDRESSES section of this preamble).

A. Applicability Provisions and Definitions

1. General Applicability: Definition of Pharmaceutical Product

At proposal, pharmaceutical product was defined as "any material described by the Standard Industrial Classification (SIC) Code 283, or any other fermentation, biological or natural extraction, or chemical synthesis product regulated by the Food and Drug Administration, including components (excluding excipients) of pharmaceutical formulations, or intermediates used in the production of a pharmaceutical product." Many commenters stated that, based on the proposed definition of pharmaceutical product, the general applicability of the standard is too broad, ambiguous, and appears to overlap with other MACT standards that cover the chemical industry. Comments on the definition of pharmaceutical product focused on the following four areas: (1) the use of Standard Industrial Classification (SIC) codes, (2) the scope of products regulated by the FDA, (3) the meaning of the term "intermediates," and (4) the exclusion of specific products/processes.

Many commenters suggested that instead of referencing SIC code 283, the definition of pharmaceutical product should be narrowed to include only SIC codes 2833 and 2834

because facilities classified under these two SIC codes produce pharmaceuticals as their primary product, and were the source of information and data that formed the basis for the proposed rule. Two other commenters stated that the use of SIC codes or the new North American Industrial Classification System (NAICS) codes in defining pharmaceutical products was inappropriate because of the ambiguous nature of SIC and NAICS code applicability, and that instead of using SIC or NAICS codes, the definition should clearly describe the characteristics of the processes that are subject to the rule. One of the commenters also provided a recommended definition of pharmaceutical product based upon the definition of "drug product" already established by the Food and Drug Administration at 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs).

Many commenters stated that the inclusion of the phrase, "regulated by the Food and Drug Administration" should be deleted from the definition of pharmaceutical products because many nondrug products such as cosmetics, food additives, plastics (food contact films) and dietary supplements, are regulated by the FDA and could be interpreted as being pharmaceutical products based on the proposed definition of pharmaceutical product. However, another commenter requested that EPA expand the definition

of pharmaceutical products to include products regulated by the U.S. Department of Agriculture (USDA) as well as the FDA because the pharmaceutical industry produces animal biologics using the same processes used to produce human biologics, and therefore, HAP emitted from the production of animal biologics also should be regulated as part of the pharmaceutical NESHAP.

Many commenters stated that the use of the term "intermediates" in the definition of pharmaceutical product was confusing and brings many unintended chemicals and processes into the pharmaceutical NESHAP; and therefore, the term should be either clarified or deleted from the definition of pharmaceutical product. One commenter stated that inclusion of the term, "intermediate," in the definition of pharmaceutical product makes it unclear how far back in the manufacturing chain a regulated entity must look when determining applicability. Many commenters stated that operations that manufacture raw materials (such as acids and solvents) that are not precursors to active ingredients in pharmaceutical products should not be regulated as part of the pharmaceutical NESHAP. Several commenters stated that the rule should only apply to processes which produce materials which exclusively or primarily are used to make drug active ingredients. Another commenter stated that EPA

needs to clarify that intermediates already regulated by the HON are excluded from the pharmaceutical NESHAP.

Four commenters requested that EPA specifically exclude certain “nonpharmaceutical products” from the definition of pharmaceutical product. One commenter expressed concern that due to the inclusion of SIC code 2835 and the phrase, “regulated by the FDA,” in the pharmaceutical product definition, equipment used to manufacture medical devices or substances used in the manufacture of medical devices could be subject to the pharmaceutical NESHAP instead of the miscellaneous organic NESHAP (MON). Therefore, the commenter requested that “medical devices” be specifically excluded from the definition of pharmaceutical product. A second commenter stated that the rule should not apply to specialty chemical manufacturers who occasionally engage in tolling a pharmaceutical intermediate. The commenter further stated that tolling of pharmaceutical intermediates could be driven overseas if U.S. specialty chemical operations require long lead times to identify MACT requirements, develop compliance systems, and amend title V requirements. A third commenter suggested that EPA exclude contract manufacturing from the pharmaceutical rule, and allow it to be covered by the MON. The fourth commenter requested that EPA specifically exclude “color additives and other inactive ingredients” from the definition of pharmaceutical product

because the commenter interpreted EPA's exclusion of excipients from the definition of pharmaceutical product to mean that the pharmaceutical NESHAP was only intended to cover active ingredients. The fourth commenter also provided a definition of excipients developed by the International Pharmaceutical Excipients Council.

The EPA considered all of the above comments and revised the definition of pharmaceutical product based on these and other considerations. The rationale for the revised definition is presented below.

The EPA agrees with the commenters that SIC codes may be ambiguous, were not developed with environmental regulation in mind, and may not reflect individual processes within a facility, and therefore, that the use of SIC codes to define pharmaceutical product may introduce unintended ambiguity into applicability determinations. Also, EPA believes that the use of the newer NAICS codes in defining applicability would result in the same problems with ambiguity and intended use. However, based on industry survey responses, EPA recognizes that facilities primarily claiming SIC codes 2833 and 2834 and/or NAICS codes 325411 and 325412 produce medicinals and pharmaceuticals as their primary products. Therefore, for the sake of clarity and consistent with the survey responses, EPA has retained the

SIC Codes and added the NAICS codes in the definition of pharmaceutical product.

The EPA also agrees that the term “regulated by FDA” is also ambiguous. As noted by one commenter, in 21 CFR section 207.10(e), FDA exempts from registration and drug listing, “manufacturers of harmless inactive ingredients that are excipients, coloring, flavorings, emulsifiers, lubricants, preservatives, or solvents that become components of drugs, and who otherwise would not be required to register under this part.” The EPA agrees that some of the processes used to manufacture such substances were not intended for coverage by this rule, and that was the intent of including the phrase “regulated by FDA” in the definition of pharmaceutical product in the proposed rule. Based on the comments, EPA believes that a less ambiguous way to define pharmaceutical product would be to base it on definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General) for drug product or active ingredient. These definitions capture formulation products as well as pharmaceutical active ingredients and their precursors.

The proposed rule also was intended to cover intermediates that are manufactured prior to the final processing steps in which a compound becomes a pharma-

ceutical product. However, EPA recognizes the difficulty associated with defining an intermediate, especially the point at which a chemical becomes associated with pharmaceutical manufacturing. Because the pharmaceutical industry is characterized by numerous processes that may be conducted prior to the actual synthesis and isolation of active ingredients, EPA rejects the notion that, in order to simplify applicability, only those processes yielding active ingredients should be covered by the rule. Rather, EPA agrees with the suggestion that the rule be based on the primary intended use of the materials manufactured. By defining applicability according to primary use as pharmaceutical products or as their precursors, intermediates that are further processed to become active ingredients or drug components are covered. Therefore, in order to clarify the boundaries of the coverage of such precursors or intermediates, the definition of process was changed in the final rule to clarify that the provisions of the subpart apply to materials whose “primary use” is as a pharmaceutical product or precursor.

The “primary use” approach also addresses the comment regarding the exclusion of contract manufacturing from the pharmaceutical rule. Simply put, contract manufacturers will be subject to this standard during periods when they manufacture a pharmaceutical product. To simplify the

determination of applicability for facilities that conduct contract manufacturing, some commenters suggested that the rule apply to processes whose primary product is a pharmaceutical active ingredient. The concept of primary product has been used in past regulations (e.g., HON, P&R IV, etc.) and was not considered in the proposed rule because there was a conscious effort to disengage production equipment from products manufactured. Because the standards are process-based, the intent of the proposal was to cover the production of pharmaceutical products, regardless of what pieces of equipment were used to manufacture them in the course of a year. Conceptually, the primary product definition makes sense for process lines that can be used to manufacture more than one product. In the pharmaceutical manufacturing industry, however, process equipment is reconfigured such that the same pieces of equipment may not always be part of the same process line. Under the current concept of primary product that appears in other rules, it would still be difficult to determine the primary product of a nondedicated process, because not all the same equipment would be associated with the “process.” However, by reverting back to the concept of “primary use,” owners and operators can clearly delineate applicability based on the intended use of materials they manufacture, and not the equipment they are manufactured in.

The revised definition for pharmaceutical product in today's final rule borrows heavily from definitions contained in 21 CFR 210.3 (Current Good Manufacturing Practice in Manufacturing, Processing, or Holding of Drugs; General). The revised definition of pharmaceutical product and a new definition for primary use are shown below. Also, definitions for "active ingredient," "component," and "excipient" have been included in today's final rule.

Pharmaceutical product means: (1) any material described by the standard industrial classification (SIC) code 2833 or 2834; (2) any material whose manufacturing process is described by the north american industrial classification system (NAICS) code 325411 or 325412; (3) a finished dosage form of a drug, for example, a tablet, capsule, solution, etc., that contains an active ingredient generally, but not necessarily, in association with inactive ingredients; or (4) any component whose intended primary use is to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals (the term does not include excipients, but includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients).

Primary use means the single largest use of a material.

For reasons described above and in response to related comments, the applicability language in § 63.1250(a) also has been changed in the final rule such that the rule only applies to those pharmaceutical manufacturing operations that meet the following criteria: (1) they manufacture a pharmaceutical product, as defined in section 63.1251, (2) they are located at a plant site that is a major source as defined in section 112(a) of the Act, and (3) they process, use, or produce HAP. The third criterion was included in response to one commenter's concern that, while the rule covers all processes at a facility which is determined to be major source, some processes at those major sources do not emit HAP. The commenter also stated that although this situation may not pose a significant compliance problem, the lack of an exclusion for these non-HAP emitting processes posed an unwarranted regulatory burden. The EPA agreed with the commenter, and modified the applicability of the rule as described above.

2. Definition of PMPU and Pharmaceutical Manufacturing Operations

The EPA received several comments on the proposed definitions of PMPU and pharmaceutical manufacturing operations. At proposal, PMPU was defined as "any processing equipment assembled to process materials and manufacture a pharmaceutical product and associated storage tanks, waste-

water management units, or components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product." Pharmaceutical manufacturing operations were defined to "include PMPU's and other processes and operations as well as associated equipment such as heat exchange systems that are located at a facility for the purpose of manufacturing pharmaceuticals."

One commenter stated that having both "pharmaceutical manufacturing operation" and PMPU in the proposed rule was confusing and redundant. The commenter stated that by having both terms, the rule implies that the definition of PMPU does not cover all of the equipment to be regulated by subpart GGG. The commenter further stated that the inclusion of the phrase "associated equipment" in the pharmaceutical manufacturing operations definition was unclear because the definition of PMPU already covers "associated" equipment. The commenter also stated that heat exchangers were given as an example of "associated equipment" under the definition of pharmaceutical manufacturing operation, but not included as an example in the definition of PMPU. For these reasons, the commenter suggested that the definition of pharmaceutical manufacturing operation be deleted entirely, and that heat exchangers be added to the

list of examples of “associated equipment” in the PMPU definition.

Two commenters stated that wastewater management units should not be included in the definition of PMPU. One commenter stated that wastewater management units are not subject to the standard, but instead are used to comply with the standard. This commenter also pointed out that neither the HON’s definition of chemical manufacturing process unit (CMPU) nor the Polymers and Resin I NESHAP definition of elastomer product process unit (EPPU) includes wastewater management units. The commenter further stated that including wastewater management units in the definition of PMPU could be interpreted to require new source MACT at an existing wastewater management unit if a new, major, dedicated PMPU is built that will contribute wastewaters to that unit. Another commenter stated that packaging operations (e.g., “placement of dose forms, such as tablets, into containers, and assembly, closure, and labeling of these containers”) are not pharmaceutical manufacturing operations, and thus, should be explicitly excluded from the definition of pharmaceutical manufacturing operations.

Many commenters stated that the definition of PMPU should be modified to make it clear that a PMPU is a group of equipment. These commenters were concerned that, as written, the definition of PMPU could be interpreted to mean

that an individual piece of equipment constitutes a PMPU, and thus, the addition of a single piece of equipment to an existing dedicated process line could trigger new source MACT.

Many commenters stated that a PMPU should be identified by its primary product and suggested adding language to the definition that makes it clear that PMPU's manufacture pharmaceutical products as their primary product.

After consideration of the above comments on the definitions of pharmaceutical manufacturing operations and PMPU, EPA has decided to retain both terms, but with some modifications. The terms "Pharmaceutical Manufacturing Operations" and "Pharmaceutical Manufacturing Process Unit (PMPU)" were not intended in the proposed rule to refer to the same sources entirely. While the term "Pharmaceutical Manufacturing Operations" is the broadest term used in the rule and covers all emission sources within a given facility that are the direct or indirect result of pharmaceutical manufacturing, the term "PMPU" was intended to encompass each process unit within the facility and its associated equipment. Therefore, the pharmaceutical manufacturing operations encompasse all PMPU's at a given facility as well as equipment that is not included in individual PMPU's. In the proposed rule, the PMPU was used exclusively to define new source applicability in § 63.1250(c). In today's final

rule, PMPU's also have replaced "processes" in the pollution prevention standard, and therefore, PMPU's serve several functions in the final rule. The PMPU also serves as the basis of the wastewater cutoffs for the standard, at 1 Mg/yr applicability HAP load per PMPU. The EPA believes that the broader term for pharmaceutical manufacturing operations is necessary to include sources that cannot be associated with single PMPU's.

By including wastewater management units in the definition of PMPU at proposal, EPA intended that all wastewater streams and residuals would be considered part of the PMPU. The EPA reviewed the definition of process and PMPU for consistency with the HON and other MACT standards. Wastewater management units are subject to the standard, but manage wastewater from several PMPU. However, wastewater generated in a PMPU is not specifically defined as part of the PMPU, but rather can be associated with it. This convention is analogous to process vent emissions; although they are not specifically identified as part of the PMPU, a PMPU may generate process vent emissions. In deciding whether the PMPU has the potential to emit 10 or 25 tons of HAP, all emissions from all sources associated with the PMPU, including process vents and wastewater, must be considered. Therefore, the definition of PMPU was modified

to not specify wastewater streams, residuals, and wastewater management units, as part of the PMPU.

Although EPA recognizes that rarely will one piece of equipment comprise a PMPU, the Agency disagrees with the commenters that a PMPU must always be defined as a group of equipment. The definition of PMPU in today's final rule, however, includes the term, "process" which is defined as a "logical grouping of processing equipment which collectively function to produce a pharmaceutical product" and "may consist of one or more unit operations." However, a PMPU is not always associated with specific groupings of equipment associated with a given process. (See also section VI.A.3 of this preamble and § 63.1252 of the final rule for a complete definition of process.)

In response to suggestions that EPA define a PMPU by its primary product, the EPA has included a primary use concept in the definition of pharmaceutical product in the final rule as discussed previously in section VI.A.1, above. Based on the comments discussed above and related comments, the definitions of PMPU and pharmaceutical manufacturing operations in today's final rule are as follows:

Pharmaceutical manufacturing process unit (PMPU) means the process, as defined in this subpart, and any associated storage tanks, equipment identified in § 63.1252(f), and components such as pumps, compressors, agitators, pressure

relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used in the manufacturing of a pharmaceutical product.

Pharmaceutical manufacturing operations means the facility-wide collection of PMPU's and any other equipment such as heat exchanger systems or cooling towers, that are not associated with an individual PMPU, but that are located at a facility for the purpose of manufacturing pharmaceutical products and are under common control.

3. Definition of Process

The EPA received a number of comments on the proposed definition of process. At proposal, process was defined as "a logical grouping of processing equipment which collectively function to produce a pharmaceutical product or isolated intermediate. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate. The physical boundaries of a process are flexible, providing a process ends with a product or isolated intermediate, or with cessation of onsite processing. Nondedicated solvent recovery and nondedicated formulation operations are considered single

processes that are used to recover or formulate numerous materials and/or products."

Many commenters requested that the definition of process be clarified to indicate that Quality Assurance and Quality Control (QA/QC) laboratories are not considered part of the process. These commenters were concerned that, although it may be clear that QA/QC labs are not "processing equipment" or "an activity or an operation used to produce a product," the words, "or other activity, operation," may lead to confusion as to whether QA/QC labs are part of the process. The commenters suggested that EPA explicitly exclude QA/QC labs from the definition of process because QA/QC laboratories emit insignificant quantities of HAP, and therefore, time-consuming nonapplicability demonstrations could be avoided.

Several commenters recommended that EPA include storage tanks in the definition of process so that sources that choose to comply using the pollution prevention alternative are not exempted from the storage tank requirements in § 63.1252(b) of the proposed rule. The commenters stated that emissions from storage tanks may be significant, and that sources should be required to comply with the storage tank standards under all circumstances.

Many commenters requested that EPA modify the definition of process to clarify how the process vent provi-

sions will apply to formulation facilities. These commenters were concerned that the use of the term “nondedicated” in reference to formulation facilities results in confusion as to how to apply the standard. The commenters pointed out that, unlike equipment used in pharmaceutical chemical synthesis facilities, equipment in a formulation facility are only used to formulate products, and therefore, formulation facilities are “dedicated” to formulation operations. However, the commenters also pointed out that the equipment at the formulation facility is used to produce many different products, and therefore, is “nondedicated.” For these reasons, the commenters recommended that, for formulation operations, the term, “nondedicated,” be applied to the equipment within the facility and not the facility itself. The commenters also requested that for formulation operations, EPA limit the definition of process to formulation activities <u>within a contiguous area</u> (such as a formulation building or a contiguous area within a multipurpose building in which formulation takes place). The commenters cited examples where separate formulation operations are located at the same plant site, but are physically separate, and thus would require separate emission control systems.

Another commenter was concerned that use of the term “nondedicated” could be interpreted as including solvent recovery or formulation operations that process small

quantities of pharmaceutical-related materials, but whose primary use is for a process subject to another MACT rule. The commenter recommended that this issue be resolved by (1) deleting the term “nondedicated” from the proposed definition of process, and (2) adding the phrase, “whose primary use is associated with the manufacture of pharmaceutical products” after the word “operations” in the last sentence of the proposed definition of process.

One commenter suggested that the phrase “or isolated intermediate” (used throughout the definition) be deleted because “processes produce products,” but “portions of processes produce intermediates.” The commenter further explained that although the product of one process may be used as a raw material in another process, the product serving as the raw material is not typically thought of as an intermediate.

The EPA has modified the definition of process in the final rule in response to the comments described above. The EPA agrees with the commenters that QA/QC laboratories are not part of the process, and the definition of process in the final rule excludes QA/QC laboratories.

To clarify EPA’s intention that storage tanks be included as part of the pollution prevention alternative, and in response to the comments regarding the perceived exclusion of storage tanks from the P2 alternative, today’s

final rule includes storage tanks in the definition of PMPU and refers to PMPU's instead of "processes" in the pollution prevention provisions (see also section V.A.2 of this preamble--Definition of PMPU and Pharmaceutical Manufacturing Operations, and section VI.F--Pollution Prevention Alternative).

The EPA disagrees with the commenters who believe that the term, "nondedicated," as applied to formulation facilities, should be applied to the equipment within the facility and not to the facility itself. As explained in section VI.A.1 of this preamble, the pharmaceutical NESHAP regulates processes, not equipment, and the concept of primary use is applied to the pharmaceutical product, not to the equipment used to manufacture the product. However, today's final rule clarifies the intent of the proposed rule with regard to formulation and solvent recovery operations: those operations occurring within a contiguous area are to be considered as single processes, regardless of the final product of that formulation or recovery operation.

The EPA agrees with the suggestions provided by one commenter to delete all references to "isolated inter-mediate" and has incorporated these comments into the definition of process in the final rule. Also, the definition of pharmaceutical product in the final rule (see section VI.A.1--General Applicability: Definition of

Pharmaceutical Product) states that pharmaceutical product "includes drug components such as raw starting materials or precursors that undergo chemical change or processing before they become active ingredients." Therefore, drug components such as raw materials and precursors, which are themselves products of processes, are defined as products, rather than "intermediates," thus eliminating the need for the concept of "intermediates" (see also section VI.A.6--Definition of Isolated Intermediate).

For the reasons stated above, the definition of "process" in today's final rule is as follows:

Process means all equipment which collectively function to produce a pharmaceutical product. A process may consist of one or more unit operations. For the purposes of this subpart, process includes all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a pharmaceutical product. Cleaning operations are considered part of the process. The holding of the pharmaceutical product in tanks or other holding equipment for more than 30 consecutive days, or transfer of the pharmaceutical product to containers for shipment, marks the end of a process, and the tanks are considered part of the PMPU that produced the stored material. When material from one unit operation is used as the feedstock for the produc-

tion of two or more different pharmaceutical products, the unit operation is considered the endpoint of the process that produced the material, and the unit operations into which the material is routed mark the beginning of the other processes. Nondedicated recovery devices located within a contiguous area within the affected source are considered single processes. Nondedicated formulation operations occurring within a contiguous area are considered single processes. Quality Assurance and Quality Control laboratories are not considered part of any process.

The revised definition of process provided above clarifies when a process ends. The EPA selected 30 days as a reasonable period of time, beyond which, if a material has not been further processed or reacted, a process can be considered complete for the purposes of this subpart. Applicability determinations and control requirements would be more difficult without such a time frame. The definition of process is a key element of the rule because most of the applicability and compliance determinations are based on the process, as a unit. Because of concerns that processes could be artificially divided into smaller portions of processes in order to meet the 2,000 lb/yr limit, EPA limited the number of processes per facility that can comply with the 2,000 lb/yr limit to seven per year. However, EPA also added that processes with very low emissions (less than

100 lb/yr HAP, uncontrolled) would not be counted as part of the seven process limit. These limitations and exemptions are currently under review and may be revised at a later time.

4. Definition of Process Vent

The EPA received several comments on the proposed definition of process vent, primarily related to the following two issues: (1) the establishment of a de minimis level or cutoff below which controls would not be required and (2) how the rule applies to process vents that are manifolded together. At proposal, process vent was defined as "a vent from a unit operation through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Process vents do not include vents on storage tanks regulated under § 63.1252(b), vents on wastewater emission sources regulated under § 63.1252(d), or pieces of equipment regulated under § 63.1252(e)."

Many commenters requested that EPA modify the definition of process vent to exempt any vent that contains a gas stream with less than 50 ppmv HAP averaged over the unit operation. These commenters cited 40 CFR

part 63.113(g) of the HON, which exempts vents with less than 50 ppmv from monitoring or any other provisions of sections 63.114 through 63.118. One of these commenters provided a cost analysis, using EPA's recently released biofilter cost model, for an existing fermentation operation, the emissions from which typically contain less than 50 ppmv methanol. The cost effectiveness of biofiltration for this scenario was estimated to be $27,000/Mg, with a percent control of 60 percent (i.e., from 50 ppmv to 20 ppmv, EPA's established practical limit of control), a value that the commenter stated was "clearly unreasonable." The commenter further stated that for fermenter and fermenter preparation vents, a cutoff of 100 to 200 ppmv could be justified (as opposed to 50 ppmv) and requested that EPA consider such a cutoff.

Two commenters stated that the proposed definition of process vent implies that every process vent is connected to a single piece of unit operations equipment, which often is not the case at multiproduct, multibatch facilities. One of the commenters suggested that the definition include a statement indicating that "multiproduct facilities having multiple production trains may have large numbers of process vents, which could discharge directly to the atmosphere; discharge through a dedicated control equipment; or which can be manifolded from many process units into a common

header leading to a common control equipment." The other commenter stated that compliance with the process vent standards would be more difficult and expensive if the definition of process vent included the combined or commingled vents from several pieces of unit operations equipment, rather than just one piece of equipment. This commenter also questioned if standard industrial hygiene type exhaust pickups and general room ventilation exhaust points are meant to be included in the definition of process vents. The commenter pointed out that those types of systems may exhaust through a stack, which may be interpreted as being an emission point, but noted that some states do not consider these emission points for the purposes of Title V permits. The commenter stated that, if these emission points were not considered in developing the MACT floors, they should not be included as process vents, and requested clarification from EPA.

As explained in section VI.C of this preamble, the definition of process vent in today's final rule includes a de minimis cutoff for uncontrolled and undiluted vent streams of 50 ppmv HAP. Regarding multiple vents (from the same process) being manifolded together into a common header, the Agency considers the common header in this rule to be a single process vent, and has revised the definition of process vent to reflect this view. In response to one

commenter's question about whether or not industrial hygiene exhausts and general room ventilation exhausts would meet the definition of process vent, these sources would not be considered process vents if they are under the 50 ppmv HAP cutoff. Based on the changes discussed above, the definition of process vent in the final rule is as follows:

"Process vent means a vent from a unit operation or vents from multiple unit operations within a process that are manifolded together into a common header, through which a HAP-containing gas stream is, or has the potential to be, released to the atmosphere. Examples of process vents include, but are not limited to, vents on condensers used for product recovery, bottom receivers, surge control vessels, reactors, filters, centrifuges, and process tanks. Emission streams that are undiluted and uncontrolled containing less than 50 ppmv HAP, as determined through process knowledge, test data using Methods 18 of 40 CFR part 60, appendix A, or any other test method that has been validated according to the procedures in Method 301 or appendix A of this part, are not considered process vents. Process vents do not include vents on storage tanks regulated under § 63.1253, vents on wastewater emission sources regulated under § 63.1256, or pieces of equipment regulated under § 63.1255."

5. Definition of Process Condenser

The EPA received numerous comments on the proposed definition of process condenser. These comments primarily dealt with the dual role of condensers as both process condensers and air pollution control devices, and in which category recirculating condensation systems should be classified. At proposal, process condenser was defined as "a condenser whose primary purpose is to recover material as an integral part of a unit operation. The condenser must support vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of substances(s). Examples of process condensers include distillation condensers, reflux condensers, process condensers in line prior to the vacuum source, and process condensers used in stripping or flashing operations."

Many commenters took issue with the phrase "integral part of a unit operation" and "process condensers in line prior to the vacuum source." These commenters cited examples where it could be concluded that a condenser is not integral to a process because it does not perform any necessary process function. The commenters also stated that if there were two condensers in series prior to a vacuum source, and the first condenser effected a phase change, then the second condenser should be considered an air pollu-

tion control device, even though it is located “prior to a vacuum source.”

Three commenters suggested that the intended use be considered when determining whether a condenser is a process condenser or an air pollution control device. Two of these commenters stated that, “if the condenser is acting as a control unit, so that its presence is intended to prevent chemicals from reaching the uncontrolled environment; if the materials collected are led towards management and disposal systems; and if the collected materials are in no way used, reused, nor sold for fuel value, then the condenser is serving as a control unit regardless of the fact that the bubble point is met or not at the source.” The other commenter disagreed with the condition that to be a process condenser, the condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are above the boiling or bubble point of the substance(s). This commenter pointed out that under the proposed definition, the same condenser will sometimes be a process condenser and sometimes an air pollution control device, and tracking when the condenser switches from one to the other would be burdensome. Therefore, the commenter recommended that the facility which operates the condenser (and knows the process best) be allowed to determine whether it is a process condenser or an air pollution control device.

Another commenter suggested that EPA distinguish between process condensers and condensers serving as air pollution control devices by including a specific temperature limit (i.e., 20°C) such that condensers that lower the temperature of the exit gas stream to a colder temperature would be considered air pollution control devices instead of process condensers.

Many commenters requested that EPA specifically address process condensers that belong to recirculating drying systems. Most commenters stated that condensers in recirculating drying systems should be considered pollution control devices. However, one commenter stated that recirculating condensation systems should be defined as neither process condensers nor air pollution control devices, but defined separately, with “management systems to account for their pollution prevention effects to be worked out at a later date for the promulgated standard.” The major concern of all of these commenters, however, was that under the proposed definition, the recirculating condensation systems would be considered process condensers, and thus, the uncontrolled emissions and resulting emissions reductions would be considerably lower than if the condenser was considered an air pollution control device. Even though these systems generate considerably lower emissions as compared to once-through systems, owners and operators could not take

advantage of the high emission reductions in the process vent standard that requires 93 percent control or 2,000 lb/yr after control from the entire process.

The EPA disagrees with the suggestion that the owner or operator should be allowed to determine whether a condenser is a process condenser or an air pollution control device based on "intended use." Because one of the formats of the process vent standard requires that a reduction from uncontrolled emissions be applied across a process (i.e., achieve a 93 percent reduction in emissions from the process), EPA is concerned about the opportunity for crediting reductions achieved by condensing boiling streams on other sources in the process. In fact, in requesting data from industry (which was later used to set the MACT floor), the MACT partnership specifically confirmed from responders that the data reported was based on the definition of process condenser as described in the proposed rule. Therefore, EPA has retained the intent of the proposed definition, but has made clarifying changes. The definition of process condenser in the final rule is as follows:

"Process condenser means a condenser whose primary purpose is to recover material as an integral part of a process. The condenser must support a vapor-to-liquid phase change for periods of source equipment operation that are at or above the boiling or bubble point of substance(s) at the

liquid surface. Examples of process condensers include distillation condensers, reflux condensers, and condensers used in stripping or flashing operations. In a series of condensers, all condensers up to and including the first condenser with an exit gas temperature below the boiling or bubble point of the substance(s) at the liquid surface are considered to be process condensers. All condensers in line prior to a vacuum source are included in this definition."

The EPA also rejects the suggestion to use 20°C as a temperature cutoff in determining whether a condenser is a process condenser or an air pollution control device. Because of the differences in the chemical and physical properties of substances used in the manufacture of pharmaceutical products, one temperature cannot be used to represent all processes; in some cases, a condenser operating at 20°C could actually be an air pollution control device and not a process condenser. Finally, EPA disagrees with the requests that condensers in recirculating drying systems be considered as pollution control devices or defined separately. Emissions from the recirculating drying systems only occur during periodic depressurizations, and these uncontrolled emissions may be low enough such that the process may be under the 2,000 lb/yr cutoff. Processes with recirculating drying systems also may be able to take advantage of the pollution prevention standard.

6. Definition of Isolated Intermediate

At proposal, isolated intermediate was defined as “any intermediate that is removed from the process equipment for temporary or permanent storage or transferred to shipping containers.” The concept of an intermediate was also included in the proposed definition of pharmaceutical product which contained a reference to “intermediates used in the production of pharmaceutical products (see section VI.A.1 of this preamble). One commenter on the proposed rule stated that EPA should not use or define the term, “isolated intermediate,” in the pharmaceutical NESHAP. (The same commenter also stated that the term, “isolated intermediate,” should be removed from the definition of process [see also section VI.A.3--Definition of Process].) The commenter pointed out that the term is “peculiar to the Toxic Substances Control Act (TSCA), where a long history of interpretation has been developed,” and if EPA uses this same term in the pharmaceutical NESHAP, “inconsistencies in interpretation will be inevitable.”

Many other commenters suggested that the definition of isolated intermediate be modified so that the physical removal of an intermediate from the process equipment is not required as a condition for meeting the definition of isolated intermediate. These commenters pointed out that, in some cases, an intermediate may remain in a storage tank

or other retention equipment prior to being used in a different process step, and without ever being removed from either set of process equipment. The commenters further stated that the fact that retention tanks are used as separation lines as an alternative to storing the material in drums or separate containers "is a matter of convenience." Therefore, the commenters recommended the following modified definition of isolated intermediate:

"Isolated intermediate means any intermediate that is stored in storage tanks or other holding equipment for later use, or that is transferred to containers for shipment or storage."

After considering these and other related comments (see section VI.A.3 of this preamble), EPA has deleted the term, "isolated intermediate," from the definition of process to avoid confusion and emphasize that products are the end result of processes. Therefore, isolated intermediates are no longer defined or referred to in today's final rule. Also, the definition of process in the final rule incorporates the commenters' suggestion above regarding the fact that physical removal of the "product" from the process equipment should not be a required condition for meeting the definition of "product." In addition, the definition of process in the final rule specifies when a process "ends."

7. Research and Development Facilities

Many commenters expressed support for the proposed definition of research and development facilities because it draws a clear distinction between activities related to manufacturing (which are covered under today's final pharmaceutical production NESHAP) and those related to research and development (which are not covered by today's final rule). The commenters further stated that such a clear distinction is necessary because pharmaceutical manufacturing operations and research and development activities are often located at the same site. Many commenters requested that EPA make it clear that pilot plants are not subject to the proposed pharmaceutical standards if they meet the definition of "research and development facility." In determining whether an operation of facility constitutes a research and development facility, it is EPA's intention that owners and operators and implementing agencies should refer to the definition of research and development facility which appears in Section 112(c)(7) of the Clean Air Act, rather than relying on existing company designations or facility names. For example, if a pilot plant is collocated with pharmaceutical manufacturing operations that are subject to this subpart, and the pilot plant meets the criteria outlined in the definition of research and develop-

ment facility, then the pilot plant would not be subject to this subpart.

Two commenters were concerned that the term “de minimis,” as it is used in the definition of research and development facility, was not defined in the proposed rule. One of the commenters stated that, without clarification (of de minimis) the definition will lead to exhaustive and potentially contentious negotiations between sources and regulatory agencies, and may result in inequitable exemption decisions at similar facilities located in different jurisdictions. The commenter also pointed out that some States have included more specific provisions, such as limiting the number of products produced, establishing maximum daily emission rates, or requiring segregation of the R&D activities from the production areas. Although EPA recognizes the concerns of the commenters, today’s final rule does not establish a de minimis level for research and development facilities. The EPA does not have sufficient data to establish a de minimis level, and therefore, such determinations will have to be made by the applicable permitting authorities. Also, EPA is in the process of collecting background information on the various segments of research and development facilities nationwide and is considering development of a NESHAP for one or more of these segments in the future.

8. Consistency with Other Rules

The EPA received numerous comments regarding the potential for overlapping regulations. Commenters were strongly opposed to the idea of the same sources being subject to multiple regulations and asked EPA to clarify which regulations applied to pharmaceutical manufacturing operations.

The EPA has identified several potential areas in which today's final standards, the RCRA standards (subpart AA or CC), and/or subpart I of 40 CFR part 63 could apply to the same situation. To avoid inconsistent requirements, the EPA has tried to make the regulatory language as specific as possible as to which regulation(s) the owner or operator must comply with to satisfy the requirements of all regulatory programs. For example, if an air pollution control device is subject to the pharmaceuticals production NESHAP and RCRA requirements, § 63.1250(h)(2) of today's final rule states that the owner or operator may elect to comply with the monitoring, recordkeeping and reporting requirements of either rule, as long as they identify which rule's requirements they have selected in the Notification of Compliance Status report. However, if the owner/operator elects to go with RCRA requirements, there may be additional (minimal) reporting requirements.

Similarly, §§ 63.1250(h)(1), (3) and (h)(4) address overlap with other MACT standards, subpart Kb (the NSPS for organic liquid storage tanks), and subpart I (the negotiated regulation for equipment leaks). After the compliance date for today's final rule for pharmaceuticals production, an affected source subject to Subpart I is required to comply only with the provisions of today's final rule. For sources subject to other MACT standards and NSPS Kb, reporting requirements may be streamlined to the extent that the rules are consistent.

B. Storage Tank Provisions

The proposed and final standards for storage tanks with capacities greater than 20,000 gallons (i.e., reduce HAP emissions by at least 95 percent) represent a control level that is beyond the MACT floor. In deciding to go beyond the MACT floor, EPA determined that floating roof technology was less costly than condensers (which represented the MACT floor technology and 90 percent control) and resulted in greater emission reductions. Many commenters stated that the proposed requirements for storage tanks with capacities greater than or equal to 20,000 gallons represent an increase in stringency (beyond the MACT floor) without precedent. These commenters suggested that 90 percent control of HAP emissions was more appropriate and consistent with the storage tank provisions of similar rules (e.g., the

HON and 40 CFR 60, Subpart Kb). The commenters also questioned EPA's assumption that floating roof technology could and would be used to reduce emissions from storage tanks, given the general lack of storage tanks at pharmaceutical manufacturing facilities that are fitted with floating roofs and the use of horizontal storage tanks (which cannot be fitted with floating roofs) at some facilities.

In addition, commenters requested that EPA include in the final rule: (1) an exemption for storage tanks emitting less than 500 lb/yr of HAP (an alternative that was considered and then dropped during the regulatory review process), and (2) a provision that allows vapor balancing systems as an alternative means of control. The commenters reviewed what was gained by dropping the 500 lb/yr cutoff alternative and concluded that in the top 12 percent of storage tanks, the associated emissions that would not be controlled under the 500 lb/yr cutoff alternative are 2,710 lb/yr (or 150 lb/yr/ tank). Based on an annualized cost of $142,500/yr (to control the 2,710 lb/yr), the commenters determined that the cost effectiveness of controlling the emissions from storage tanks with emissions less than 500 lb/yr would be $115,913/Mg. The commenters further stated that the EPA has authority under the law to establish de minimis provisions for exceptions from statutory directives when the benefits of regulation are

significantly outweighed by the associated costs and other burdens, and the 500 lb/yr cutoff alternative meets the criteria for establishing such a de minimis provision, especially considering the fact that the proposed storage tank provisions represent a control level above the MACT floor.

Many commenters stated that the rule should specify that vapor balancing systems meet the requirements of the storage tank provisions. The commenters stated that vapor balancing systems are effective, relatively easy to use, capable of achieving control efficiencies as high as 90 to 98 percent, and are accepted under other rules (both NSPS and NESHAP), and therefore, should be accepted in the pharmaceutical NESHAP. One commenter also pointed out that, when vapor balancing is used (i.e., the storage tank vapor space is routed to the truck), the source of pollution is the vapor content of the truck; however, when the storage tank is vented to a control device, there are two sources of pollution: the HAP vapor from the truck and secondary pollutants from the control device. The same commenter recommended that the State of New Jersey requirements for vapor control (7:27-16.4 VOC Transfer Operations, Other Than Gasoline) be incorporated into the storage tank provisions.

In response to the comments on the proposed storage tank provisions, today’s final rule does not include

provisions for vapor balancing of storage tanks. However, this issue will be addressed in the Organic Liquids distribution MACT standard. The MACT floor for storage tanks was determined to be 90 percent control of HAP from storage tanks and did not cover tank truck vapor. The EPA also considered the commenters' request for a 500 lb/yr cutoff, but rejected it because a sufficient number of small storage tanks in service at pharmaceutical manufacturing facilities are controlled, and the 500 lb/yr cutoff represents an alternative that is less stringent than the MACT floor, and thus, is not acceptable. The control level for storage tanks with capacities greater than or equal to 20,000 gallons in the final rule is the same as proposed level (i.e., 95 percent). As explained in the Basis and Purpose Document (see Docket A-96-03, Item No. III-B-01), EPA chose 95 percent control (as opposed to the MACT floor) for storage tanks greater than 20,000 gallons because floating roof technology has been demonstrated to achieve 95 percent control and is considerably less expensive than other technologies. Although floating roofs currently may not be in use on storage tanks in the pharmaceutical industry, EPA is not aware of any technical obstacles to their use, except in the case of horizontal tanks. Also, owners or operators still have the option of using add-on controls instead of floating roofs.

C. Process Vent Provisions

The EPA received numerous comments on the proposed standards for process vents. Comments focused on the following areas: (1) establishment of a concentration-based applicability cutoff, (2) implementation of the 98 percent control requirement, (3) new source MACT for process vents, and (4) compliance periods.

1. Applicability Cutoff

Many commenters suggested that EPA establish a concentration threshold below which an emission stream would not be considered a process vent, and thus would be exempt from further applicability determinations, control or monitoring requirements. The commenters recommended a de minimis concentration of 50 ppmv or 50 ppmw for process vents.

After consideration of the above recommendations and comments related to the alternative standard (see section VI.G of this preamble), EPA decided to establish a de minimis cutoff for process vents equal to 50 ppmv HAP, based on uncontrolled, undiluted emissions. The de minimis cutoff is incorporated into the definition of process vent, which states that uncontrolled, undiluted emission streams containing less than 50 ppmv HAP are not considered process vents.

2. Implementation of the 98 Percent Control Requirement

Today's final rule requires facilities to apply an equation in § 63.1254(a)(3) to determine if emissions from the process vent must be controlled by 98 percent as opposed to 93 percent. The applicability equation uses two variables, vent flow and yearly uncontrolled HAP emissions, to calculate a flow rate. The calculated flow rate is then compared to the process vent's actual flow rate, and if the actual flow rate is less than or equal to the calculated flow rate, the process vent requires 98 percent control. A number of commenters believe that the 98 percent control applicability equation should be deleted because it will create a significant recordkeeping burden, will be practically impossible to implement, and will significantly hamper operational flexibility.

The major concern noted by the commenters was that the applicability equation, though fairly straight-forward for dedicated single-product processes, is extremely difficult if not impossible to apply to multipurpose nondedicated processes. The commenters stated that, because nondedicated processes use individual pieces of equipment to make numerous products over the course of a year, the emission stream characteristics of the associated process vents will change depending on the product being manufactured, and

thus, the recordkeeping requirements for a single process vent would be burdensome. The commenters also pointed out that a facility may have 200 to 300 individual process vents.

Another concern raised by the commenters was that a slight variance from forecasted production could result in a process vent previously required to control emissions by 93 percent to become subject to the 98 percent control requirement, and the affected facility would not have sufficient lead time to upgrade their control equipment from 93 to 98 percent. The commenters were concerned that such uncertainties will hamper operational flexibility because facilities will be forced to impose limitations on production to ensure that they will not trigger 98 percent control. The commenters also stated that applying the applicability equation to manifolded vents would further complicate matters because more sources emitted through the same vent will result in greater variability of vent stream characteristics.

The commenters also requested that if EPA retains the 98 percent control requirement for existing process vents in the final rule, that § 63.1252(c)(4) in the proposed rule be revised to clearly describe how to apply the 98 percent control applicability equation. Commenters noted that using the past actual annual HAP emissions versus projected annual

HAP emissions in the applicability equation is an issue because the production of many products varies from year to year, and historical and forecasted annual HAP emission estimates may be very different. The commenters also were concerned that the proposed rule did not clearly establish how to determine the process vent's actual flow rate, which will be compared to the applicability equation's calculated flow rate. Finally, the commenters suggested that EPA specify that the applicability equation applies to individual pieces of equipment in a formulation facility. The commenters were concerned with how the applicability equation would be applied to nondedicated formulation facilities. The commenters pointed out that nondedicated formulation facilities often use multiple pieces of the same equipment to perform one operation (e.g., six tray dryers), and not all of these pieces of equipment will be used to produce every product in the formulation facility (i.e., not all trays of the dryer are always used).

After considering the comments above, EPA decided to retain the 98 percent control requirement for existing process vents that meet the applicability criteria. (For those process vents already controlled to 93 percent prior to April 2, 1997, no additional control is necessary.) The applicability equation applies to individual process vents within a process; however today's final rule considers

manifolded process vents within each process to constitute a single process vent. With the exception of formulation operations and recovery devices, the definition of process is based on the product manufactured, not the equipment used to manufacture it. Therefore, the determination of which vents require control to the 98 percent level for nondedicated process vents should be straightforward; namely, owners and operators need to anticipate the total uncontrolled HAP emissions per year from each vent from each process, and the average flow rate of the vent. The total uncontrolled emissions should be based on the potential number of batches per year that the facility can run for each process. Based on this projection, the owner or operator can decide whether to install or use an existing 98 percent control device or limit the number of batches to stay below the applicability threshold. Today's final rule also requires facilities to keep track of the number of batches of products they make each year to show that their number of batches is less than the number needed to trigger 98 percent.

In response to the commenters' request, the average flow rate has been clarified in the final rule to mean the weighted average flow rate of the emission events contributing to the process vent. For solvent recovery or formulation operations, the definition of process in today's

final rule has been clarified to include all operations within a contiguous area; therefore, for these operations, a single process may be associated with several products. Like other processes, the application of the 98 percent control applicability equation should be based on individual process vents or manifolded vents. Thus, if each piece of equipment that is located at a formulation facility, considering processes by contiguous areas, has a separate vent, then the applicability equation is applied to each vent separately; however, if the vents from each piece of equipment are manifolded together, then they are treated as one process vent and the equation is applied to the aggregated flow.

As part of the rationale for retaining the 98 percent requirement, EPA notes that this level of control is imposed only on vents that have the potential to emit 25 tons/yr or more, on an uncontrolled basis. Secondly, the applicability equation is indexed on cost-effectiveness. Streams that are too dilute for cost effective control would not, per the equation, be required to be controlled. Third, process vents already controlled to levels of 93 percent or greater prior to April 2, 1997, would be grandfathered and not required to increase controls to 98 percent. The EPA believes that after these considerations are made, only very

large streams that are cost effective to control to 98 percent will trigger the 98 percent control requirement.

3. New Source MACT for Process Vents

At proposal, new source MACT for process vents was set at 98 percent control for process vents with uncontrolled emissions greater than or equal to 400 lb/yr. The rationale for the 400 lb/yr cutoff (uncontrolled) was that it represented the smallest controlled process considered to be a similar source. Many commenters stated that the standard for new process vents should include a 2,000 lb/yr controlled emissions compliance alternative, because it is unreasonable and unwarranted to require vents with low HAP emissions to achieve 98 percent control. The commenters agreed with EPA's conclusion that 98 percent control represents the best controls in practice for certain sources; however, the commenters believe that the applicability cutoff for new source MACT for process vents is legally flawed because the cutoff did not consider two of the four process types in the industry (fermentation and extraction). The commenters also stated that the process on which the 400 lb/yr cutoff is based is not representative of the industry's processes because the process emits primarily one HAP (methanol) and is controlled by a dedicated scrubber and appears to be only a portion of a process based on the EPA's definition of process in the proposed rule. Citing

other rules that set new source MACT as the average level of control achieved by sources using new source MACT control technology, the commenters performed an analysis of the MACT floor data base and determined that the average level of controlled emissions from the best-performing 12 plants was approximately 1,400 lb/yr. The commenters excluded two processes from their analysis that had uncontrolled emissions greater than 1 million lb/yr because these processes are much larger than the typical pharmaceutical manufacturing process and would skew the data. According to the commenters, if these two (larger) processes are included in the analysis, the average level of controlled emissions from the best-performing 12 plants would equal 6,400 lb/yr.

The EPA has reviewed the data used to set the MACT floor for process vents at new sources. Based on this review, the EPA has concluded that the data support the level of the proposed standard for new sources.

The EPA based the 98 percent control requirement on the 26 processes (under the proposed definition) at 7 plants in the data base that achieve or exceed this control level. These processes include dedicated and nondedicated formulation, chemical synthesis, and fermentation processes. The EPA has concluded that these processes are representative of the control challenges faced by the industry despite the fact that the data do not include an extraction process.

The EPA has further concluded that the 98 percent control level achieved at the best controlled processes is applicable to all four process types.

The EPA does not believe that the variation in exhaust gas characteristics among the four types of processes in the industry is significant enough to warrant individual evaluation of achievable control levels. In any case, extraction processes are typically solvent-intensive, resulting in the highest average HAP concentration of the four types of processes. High HAP concentrations are conducive to high percent control levels.

The commenters suggested that the EPA adopt a 2,000 lb/yr actual emissions compliance alternative to account for variability within the industry. The commenters based this alternative on the average level of controlled emissions from 24 of the processes in the data base that achieve 98 percent control or greater. (The commenters excluded the other two processes in the data base because they were atypically large.) The EPA does not believe that the analysis presented by the commenters is an appropriate basis for a new source compliance alternative. First, while the commenters imply that the alternative is needed to account for variability in the control level that is achievable by the wide variety of pharmaceutical processes, the analysis does not address control efficiency at all.

Because the commenters evaluated only processes that achieve at least 98 percent control, only variability in uncontrolled emissions truly figures into the analysis. Second, the alternative standard suggested by the commenters is not equivalent to the percent reduction standard and would result in greater total emissions of HAP from the industry. Finally, the EPA analyses cited as precedents address different situations and provide scant support for the commenters' analysis.

While the EPA has rejected the alternative standard suggested by the commenters, the final rule provides a 20 ppmv outlet concentration alternative to 98 percent control for process vents at new sources. This alternative addresses the primary impediment to achieving 98 percent control, i.e., low inlet concentration gas streams.

The EPA based the proposed applicability cutoff for new source process vents on the smallest representative process in the data base that achieves 98 percent control or greater. The commenters questioned whether this operation actually qualifies as an entire process under the proposed definition of "process" and whether the operation is representative of processes in the industry. Although the EPA continues to believe that the formulation operation selected as the basis for the proposed cutoff is a process under the proposed definition, it may not qualify as a

process under the final definition because nondedicated formulation operations occurring within a contiguous area are now considered single processes. Consequently, the EPA has reanalyzed the data based on the final definition of "process." In light of the new analysis, it is no longer relevant whether the process upon which the proposed cutoff was based is representative of the industry.

The new analysis was similar to the original analysis. After revising the data base of well-controlled sources to conform to the final definition of "process," the EPA identified the smallest processes that are controlled by 98 percent or more. As in the previous analysis, formulation and chemical synthesis processes are the smallest processes. Two chemical synthesis processes, one emitting 85 lb/yr uncontrolled and another emitting 304 lb/yr uncontrolled, were identified as achieving control of 98 percent. Although these processes were reported as individual (single) processes, EPA summed emissions from both, since the product name listed for each was very similar, and EPA wanted to be conservative. The total uncontrolled emissions from the sum of these two processes is 390 lb/yr, which is the same level of emissions as the proposed cutoff. Therefore, the EPA has established in the final rule the new source process applicability cutoff of 400 lb/yr of uncontrolled HAP.

Despite the fact that no fermentation or extraction processes were among the smallest well-controlled processes, the EPA believes that the analysis is representative of the control capabilities of all process types. As discussed previously, the EPA has concluded that the gas streams generated by the four types of processes in this industry are similar enough that an individual analysis by process type is not warranted. Fermentation and extraction processes are typically much larger than formulation and chemical synthesis processes. Thus, the absence of fermentation and extraction processes in the list of the smallest well-controlled processes is the result of this size differential, not a difference in the control level that can be achieved. In fact, the average uncontrolled HAP concentration of fermentation and extraction process vents exceeds those of formulation and chemical synthesis process vents. Higher concentrations are more conducive to high percent control.

Practically speaking, new source MACT will apply to low HAP-emitting processes only at new facilities, where the minimum control requirement is 98 percent for all processes. (At existing sites, new source MACT will apply only to dedicated new PMPU’s with a potential to emit 10 tons/yr of a single HAP or 25 tons/yr of all HAP combined.) Thus, sources will not be faced with the need to install

98 percent-efficient controls dedicated to small new processes, which could be very costly for a small amount of emission reduction. Instead, the EPA expects that sources will achieve the new source MACT standard using large control devices that treat multiple manifolded gas streams. Because this is the control situation most typically found for the small processes in EPA's data base of well-controlled sources, the EPA believes that the final rule's applicability cutoff accurately reflects what will be achievable at new sources in this industry.

4. Compliance Period

Several commenters stated that they support the proposed annual compliance period for process vents and noted the inconsistency with the daily continuous compliance provisions. If the final rule includes a shorter compliance period, the commenters have stated that either the standards must be adjusted to avoid an increase in stringency above the floor or a demonstration must be made that the increased stringency (i.e., going above the floor) is justified according to the requirements of the Clean Air Act. The EPA, in the final rule, has clarified the compliance period of the standard to be either on a 24-hour basis, or on a batch cycle or "block" basis. Additionally, compliance periods for emissions averaging are on a quarterly basis, while compliance periods for the P2 standard are on an

annual basis, as calculated on a monthly or 10-batch rolling average. An annual compliance period for the standards was determined by EPA to be too difficult to implement. The annual compliance period implies that owners and operators could control processes to varying degrees during the course of a year, as long as the yearly percent reduction target could be met. While this format would offer flexibility to owners and operators that would want to change control strategies to accommodate production scheduling and operational changes, EPA believes that the demonstration of compliance over such an extended time period would result in delayed compliance determinations and the possibility for extended periods of violations. The EPA notes that the final rule offers some flexibility to owners and operators in addressing variability within the processes themselves by providing numerous compliance options. Therefore, EPA does not believe that by clarifying the final rule to reflect a daily compliance period, the stringency of the standard was increased.

D. Wastewater Provisions

1. MACT Floor

The EPA estimated that 101 pharmaceuticals facilities would be major sources subject to the rule. The MACT floor is based on available information about control levels at all of these sources. One commenter asserted that the

applicability section of the proposed rule covers more types of facilities than those in the original MACT floor analysis, and thus the MACT floor should be recalculated. The EPA did not recalculate the MACT floor because, as noted in section VI.A.1 of this preamble, the applicability in the final rule is clarified to eliminate the likelihood that the rule would apply to types of facilities other than those represented in the 101 in the initial analysis.

2. De Minimis Cutoff in Definition of Wastewater

The final rule includes de minimis cutoffs for determining if a water stream is wastewater. One commenter requested that HAP concentration and flow rate cutoffs be added, as in the HON. The commenter contended that the burden to characterize streams with very small HAP loadings would be excessive without such cutoffs. For the final rule, EPA revised the definition of wastewater to include de minimis HAP cutoffs of 5 ppmw and 0.05 kg/yr, which is consistent with the HON. Although the owner or operator is given some flexibility in the methods used to characterize these streams, the Administrator may require the owner or operator to validate this information through sampling and analysis or other appropriate means.

3. Cross-References to the HON

The wastewater provisions in the proposed rule contained numerous cross-references to the wastewater

provisions in §§ 63.132 through 63.148 of the HON. Many commenters requested that the applicable provisions from the HON be included in the final rule because the extensive cross-referencing made the proposed rule hard to understand and would likely be hard to implement. Some comments also noted that many cross references were not consistent with the most current version of the HON. To address these concerns, EPA decided to incorporate the applicable provisions from the HON in the final rule. These provisions include the emission suppression requirements from §§ 63.133 through 63.137, the control device requirements from § 63.139, the general procedures for determining compliance from § 63.145, many of the compliance options for treatment systems and control devices from §§ 63.138 and 63.145 (additional information about compliance options is provided in section VI.D.4), the inspection and monitoring provisions from §§ 63.143 and 63.148, the requirements for certain liquid streams in open systems within a PMPU from § 63.149, and the tables that are referenced from all of these sections.

4. Additional Treatment Options for Demonstrating Compliance

Several commenters requested that the rule include additional treatment options for demonstrating compliance. Some comments requested that all of the options in the HON

be added to the rule. Other comments specifically requested that the rule allow treatment in RCRA units and that a concentration limit be developed for soluble HAP. In response to the comments, EPA included additional treatment options in the final rule that are consistent with the standards. All of the RCRA options from the HON were added because treatment in these units will meet the standards. A concentration option of 520 ppmw for soluble HAP was added because this level is consistent with the 90 percent reduction requirement for soluble HAP.

Four options from the HON were not added to the final rule. The design steam stripper option was not added because the available stripper designs that were used to estimate impacts have not been tested in the field. The percent mass removal/destruction option based on fraction removed (Fr) values was not added because the Fr values would be identical to the percent reduction option. The 1 Mg/yr option was not added because any facility with wastewater containing a load of total partially soluble and/or soluble HAP less than 1 Mg/yr would have no affected wastewater streams. The required mass removal options were not included because wastewater discharges from batch pharmaceutical processes are much more variable than those from continuous SOCMI processes; therefore, the required mass removal is likely to be different at any given time,

and is not likely to correlate well with the actual mass removal in the treatment unit at a given time.

5. General Compliance Procedures

The proposed rule cross-referenced the specific procedures in the HON for determining compliance with the standards when using various types of treatment units (i.e., noncombustion, combustion, or biological), but the general procedures used to determine compliance that are applicable to any performance test (or design evaluation) were not cross-referenced. Several commenters requested that these general procedures also be included in the rule. Specifically, the commenters requested that the rule specify that: (1) performance tests be conducted under representative operating conditions, (2) treatment may be conducted using a series of treatment devices, (3) treatment may be conducted offsite or in onsite treatment units not owned by the source, and (4) any biological units in compliance with the standards need not be covered and vented. Commenters also requested that the rule include: (1) procedures for the preparation and installation of testing equipment and (2) requirements for compounds that do not need to be considered in performance tests or design evaluations. The final rule includes all of these provisions; however, clarification of two points is provided below.

Clarification of the provision for testing under representative operating conditions is provided because the commenters misinterpreted the meaning of this provision in the HON. This provision requires a facility to conduct a single performance test under representative operating conditions. If actual operating conditions vary, such that there are multiple representative operating conditions, the owner or operator must supplement the test results with modeling and/or engineering assessments to demonstrate that the standard is met over the entire range of operating conditions. Testing under representative operating conditions does not mean the standard is an average that may be exceeded under certain conditions.

A clarification of the provision that allows open biological treatment units to be uncovered is also provided. Except for enhanced biological treatment units used to treat certain wastewater streams, an owner or operator demonstrates compliance for open biological treatment units by conducting a performance test and following the procedures in appendix C of part 63. If these procedures show the fraction biodegraded meets or exceeds the applicable control level, the treatment unit need not be covered. An enhanced biological treatment unit that is used to treat wastewater containing soluble HAP and less than 50 ppmw of partially

soluble HAP is exempt from the performance test requirements and need not be covered.

6. Default Biodegradation Rate for Methanol

One commenter urged EPA to revise the default methanol biodegradation rate constant that is used in Table 37 of subpart G of the HON because it cannot be scientifically supported with available data. Based on data from a number of studies, the commenter concluded that the rate in the proposed rule is low by a factor of 10 to 100. The commenter noted that the geometric mean of the rates from the available studies was 8.6 L/g MLVSS-hr, and the lower bound of the 90 percent confidence interval was 3.5 L/g MLVSS-hr. The commenter also cited data in the scientific literature that show hexachlorobenzene, chlorobenzene, nitrobenzene, and biphenol (other list 1 compounds) to be less biodegradable than methanol, whereas Table 37 of the HON shows methanol to be less biodegradable than the other compounds.

The data submitted by the commenter show considerable variability, but they also show the higher biodegradation rate constants tend to correspond with higher methanol concentrations in the wastewater. The EPA concluded that a methanol biodegradation rate constant higher than the default is appropriate for pharmaceutical facilities that are direct dischargers because they tend to treat wastewater

with higher methanol concentrations than indirect dischargers or facilities in other industries. The final rule allows these facilities to use a methanol biodegradation rate constant of 3.5 L/g MLVSS-hr, the lower bound of the 90 percent confidence interval; this is a conservative value that minimizes the likelihood that the biodegradation rate will be overestimated.

7. Maintenance Wastewater

The wastewater provisions apply to both process and maintenance wastewater. Commenters requested that maintenance wastewater provisions be less stringent than those for process wastewater, as in the HON. According to one commenter, the same conveyance systems and controls are not practical or cost effective for maintenance wastewater. The EPA did not change the maintenance wastewater provisions because maintenance wastewater is a potential source of significant emissions. Furthermore, procedures to estimate maintenance wastewater characteristics should be the same as those for most process wastewater because both consist of batch discharges.

8. Control Requirements for Wastewater Tanks

The rule requires that wastewater tanks have either a fixed roof or additional controls, depending on tank design and/or operating characteristics. A number of commenters expressed confusion over these provisions and offered their

interpretations or preferences to clarify the provisions. Under the rule, wastewater tanks that have a capacity of less than 75 m^3, a capacity between 75 and 151 m^3 that contain material with a vapor pressure less than 13.1 kPa, or a capacity greater than or equal to 151 m^3 that contain material with a vapor pressure less than 5.2 kPa are required to have a fixed roof unless the wastewater in the tank is heated, treated with an exothermic reaction, or sparged. If any of these three conditions is not satisfied, the owner or operator must install a floating roof or use control techniques that achieve equivalent emission reductions. These provisions match those in the HON. The proposed rule also included an additional provision that caused the confusion for the commenters. The intent of the provision was to exempt wastewater tanks from the additional control provisions, but not the fixed roof requirement, if the owner or operator demonstrates that the total partially soluble and/or soluble HAP emissions from a fixed roof tank that is heated, treated with an exothermic reaction, or sparged are less than 5 percent higher than the emissions would be in the absence of these activities. This additional provision is rewritten in the final rule to improve clarity.

9. Compliance Requirements for Biological Treatment Units

The EPA received numerous comments on the initial compliance procedures and monitoring requirements for enhanced biological treatment units. Some commenters requested that compliance demonstrations be based on parameters related to soluble HAP removal, not general compliance with all NPDES permit limits; the commenters suggested monitoring for surrogate parameters like COD, BOD, and/or TSS. Some commenters stated that EPA's definition of significant noncompliance in appendix A of 40 CFR 123.45 should be used as the basis for defining acceptable enhanced biotreatment operation for both POTW's and direct dischargers. One commenter stated that compliance provisions should focus on the indirect discharger, not the POTW; for example, the indirect discharger should be in compliance with the pretreatment provisions in 40 CFR 403 and 439. Several commenters stated that the provision allowing discharge to an enhanced biological treatment unit at a POTW only if the indirect discharger demonstrates that less than 5 percent of the soluble HAP in the wastewater from the POD's is emitted from the municipal sewer system is unnecessary and burdensome.

The compliance procedures for biological treatment units are rewritten in the final rule for clarity, simplification, and as noted above, to eliminate cross-references to the HON. Because the changes are extensive, all of the

compliance procedures and monitoring requirements for biological treatment units, not just the issues raised by the commenters, are summarized below.

Onsite or offsite biological treatment units may be used to comply with the standards for soluble HAP, and onsite biological treatment units may be used to comply with the standard for total soluble and partially soluble HAP. The compliance requirements vary depending on the concentration of partially soluble HAP in the wastewater, whether the treatment unit is open or closed, whether the biological treatment unit is enhanced, and whether the wastewater is treated onsite or offsite.

If wastewater containing soluble HAP and any concentration of partially soluble HAP is treated in an open, onsite biological treatment unit that does not meet the definition of an enhanced biological treatment unit, the owner or operator must conduct an initial performance test to determine the fraction biodegraded (f_{bio}) in the unit; the f_{bio} for the compounds may be calculated using any of the procedures in appendix C to 40 CFR part 63, except procedure 3 (inlet and outlet concentration measurements). As noted in section VI.D.5, the treatment unit may remain open if the fraction biodegraded meets or exceeds the level of the standard. For a closed biological treatment system, the owner or operator may follow the same procedure;

alternatively, the owner or operator of a closed biological treatment unit may conduct either a design evaluation using procedure 3 or a performance test to determine the mass reduction of soluble HAP (or total soluble and partially soluble HAP) in the unit. Under the proposed rule, the owner or operator of open and closed biological treatment units would have been required to specify appropriate monitoring parameters in the Notification of Compliance Status Report, subject to approval of the permitting authority. Based on consideration of the comments, EPA decided to specify continuous monitoring requirements for TSS and BOD in the final rule. To be in compliance, the TSS and BOD concentrations must not exceed the TSS and BOD criteria in 40 CFR 439 more frequently than, or by amounts greater than, allowed by the noncompliance reporting criteria in 40 CFR 123.45, appendix A.

If wastewater containing soluble HAP and more than 50 ppmw of partially soluble HAP is treated in an onsite, enhanced biological treatment system, the compliance procedures are the same as described above, except that the f_{bio} for soluble compounds may be calculated using either the default for first order biodegradation constants or any of the procedures in appendix C of 40 CFR part 63. As noted in section VI.D.6, the owner or operator may use a biodegradation rate constant of 3.5 L/g MLVSS-hr for

methanol. The owner or operator also must monitor for TSS and BOD as described above. In addition, to demonstrate continuous compliance with the 1 kg/m^3 level in the definition of enhanced biological treatment unit, the owner or operator must monitor the concentration of MLVSS.

If wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP is treated in an onsite, enhanced biological treatment unit, the owner or operator is exempt from the performance test requirement for the treatment unit. Monitoring for TSS, BOD, and biomass is required as described above.

Wastewater containing soluble HAP and less than 50 ppmw of partially soluble HAP may be transferred for offsite treatment or onsite treatment in a unit not owned by the source. Before the source may transfer such wastewater, the transferee must submit to EPA written certification that the transferee will manage and treat any affected wastewater or residuals in accordance with the requirements of the rule. The initial compliance procedures and monitoring requirements to show continuous compliance are the same as for similar onsite units treating the same wastewater. In response to the comments, EPA reexamined emissions from municipal sewer systems and determined that the major potential for emissions is from the headworks. Thus, if the wastewater is discharged to a POTW, the final rule requires

the owner or operator to demonstrate that less than 5 percent of HAPs are lost. However, if the headworks at the POTW are covered, no such demonstration is required. The same emission suppression requirements apply if the wastewater is discharged for treatment in any other type of offsite treatment unit or onsite treatment unit not owned by the source.

10. Control Requirements for Individual Drain Systems

The rule requires emission suppression and control measures for all individual drain systems that manage affected wastewater or residuals onsite. Several commenters requested that EPA exempt individual drain systems from these requirements, and allow them to be vented to the atmosphere, if they either manage wastewater that contains only soluble HAP compounds and de minimis amounts of partially soluble HAP compounds or demonstrate that emissions from the individual drain system and associated wastewater tanks are less than 5 percent of the loading in the affected wastewater. The commenter's rationale for this request was that: (1) a PhRMA study of municipal sewers, which was submitted to EPA, showed the potential emissions from individual drain systems that manage wastewater containing primarily soluble HAP are low; (2) the control is not cost effective; and (3) emissions of combustion products

would increase because facilities would meet the requirement with steam strippers or incinerators.

For wastewater, EPA determined that MACT consists of hard-piping to a steam stripper. Because this configuration was determined to be a reasonable MACT floor requirement, any alternative must achieve equivalent emission reductions. As in the HON, a covered individual drain system is considered equivalent to hard piping. Thus, EPA did not change the requirements for individual drain systems in the final rule.

E. Equipment Leak Provisions

Several commenters raised a number of issues related to equipment leaks and EPA's proposed requirements for the LDAR program developed for the pharmaceutical manufacturing industry. The proposed general equipment leak requirements in appendix A to subpart GGG were based on subpart H (from the HON rule) and included slight changes tailored for the pharmaceutical industry. Some commenters were confused by the requirements and others were concerned that some facilities will be subject to two different LDAR programs because some pharmaceutical manufacturing operations are already subject to subpart I (which requires compliance with subpart H of the HON for components at pharmaceutical production processes that use carbon tetrachloride or methylene chloride). Today's final rule clarifies EPA's

intent that affected sources that are subject to today's final rule and subpart I of 40 CFR part 63 will no longer be required to comply with subpart I after the compliance dates for today's final rule. Many commenters argued that EPA is bound by the subpart I regulatory negotiation and therefore, is not allowed to expand the LDAR requirements to include any HAP other than carbon tetrachloride and methylene chloride. The Clean Air Act requires that EPA regulate all major sources of HAP. The regulatory negotiations conducted in the development of subpart I included only a certain fraction of components from the industry because that was the extent of information that EPA had at the time the negotiations were conducted. The Agency does not agree that the negotiated rule for equipment leaks precludes further regulation of equipment leaks for pharmaceutical manufacturing operations.

Some of the changes and assumptions made in estimating the uncontrolled emissions for the industry used in determining the proposed LDAR requirements were questioned by the commenters. A group of commenters disapproved of the Agency's revised method to estimate uncontrolled emissions using the uncontrolled SOCMI average emission factors. The commenters argued that none of the studies used in developing the SOCMI emission factors involved pharmaceutical manufacturing operations.

Commenters also questioned EPA's assumptions and data used in some of the LDAR cost calculations. In general, commenters stated that the actual cost-effectiveness value associated with the proposed LDAR program was much higher than EPA's estimate due to overestimated emission reductions and underestimated costs. In response to these comments, the Agency reviewed its cost analysis and recalculated the cost effectiveness of several LDAR programs. The most acceptable program, in terms of cost effectiveness, is based on requirements similar to those of other recent regulations for similar manufacturing industries and the provisions developed for the SOCMI Consolidated Air Rule (CAR) which is yet to be proposed. The most significant difference between the CAR equipment leaks subpart and the proposed equipment leaks provisions is the innovative approach taken in the CAR to monitoring valves and connectors for leaks.

The CAR program significantly reduces the amount of burden associated with monitoring these types of equipment for leaks without increasing the emissions of regulated pollutants to the environment. In calculating the impacts of requiring an LDAR program meeting the requirements of the CAR, EPA calculated monitoring costs based on established guidance and calculated uncontrolled emissions using initial leak frequencies reported from the industry. The details of this analysis are included in the project docket (A-96-03)

as Item No. IV-B-5. The EPA, in reassessing industry leak data, addressed many of the concerns of the commenters relative to the inclusion or exclusion of specific data.

Using as a starting point leak data that was confirmed as initial survey data by PhRMA, EPA reviewed the data base and further defined the pool of data. Some data from PhRMA's compilation was revised to reflect reported leak definitions, also, some data was excluded based on the facility's explanation of frequency of monitoring and calculated leak rates and the conclusion that the leak rates did not indeed reflect initial monitoring data. The resulting initial leak rate data was 1.45 percent for valves, 6.88 percent for pumps, and 1.5 percent for connectors.

The subsequent leak rates are a critical parameter in calculating the overall cost effectiveness of any LDAR program. Limited data were available to determine the leak rates at pharmaceutical manufacturing frequencies after the application of LDAR. Therefore, EPA assumed that the equipment leak frequency occurrence rate after implementation of LDAR was equal to the performance levels required in the draft CAR, that repairs were 100 percent effective, and that there were no recurrences of leaks. For the CAR rule, where several performance levels and corresponding monitoring schedules are available, occurrence

rates were based on the best performance levels and longest monitoring intervals available. For flanges and valves, this performance level is 0.25 percent leakers. The corresponding monitoring interval for flanges is once every 8 years; for valves, it is once every 2 years. For light liquid pumps there is no performance level specified, therefore it was assumed that the leak occurrence rate was equal to 50 percent of the initial leak frequency. Subsequent leak frequencies for the revised EPA analysis were estimated to be 0.25 percent for valves, 3.44 percent for pumps, and 0.25 percent for connectors.

Emission reductions for the program were estimated to be the difference between the uncontrolled emission rate, as calculated using the mass emission rate, in kg/hr-source, calculated from the Average Leak Rate (ALR) equations and initial leak data, and the controlled emission rate, calculated using the ALR equations and assumed subsequent leak frequencies. The controlled emission rate was based on one-half of the occurrence rate. This assumption was necessary to account for the average leak frequency over the entire monitoring cycle.

EPA, in the revised analysis, also addressed concerns of the commenters related to specific cost items. In general, capital and annualized costs for monitoring instruments, data management systems, and actual monitoring

are not unreasonable and fall within the costs quoted by vendors and LDAR contract services, based on recent inquiries by EPA. Therefore, EPA did not revise significantly any cost items used in the model facility analysis.

Based on this revised analysis, the Agency found that the cost effectiveness of the CAR LDAR program was approximately $1000/Mg HAP for a model pharmaceutical facility.

After consideration of the above comments, EPA revised appendix A of subpart GGG in today's final rule to make it consistent with the Agency's recent efforts toward consolidation of equipment leak requirements for air regulations, the increased focus on processes with leaking components, and a general lessening of monitoring and recordkeeping and reporting requirements for processes with nonleaking components. Most of the changes to the proposed rule involve the requirements for valves and connectors in gas/vapor service and in light liquid service in GGGA-3 and GGGA-6. These changes include the addition of 2 year monitoring (instead of once every four quarters) for those processes with less than 0.25 percent leaking valves; extending the monitoring period for connectors with low leak rates; provisions for valve subgrouping; deletion of the quality improvement program implementation requirement and

the credit for valves removed; and revisions to the calculations for determining the percentage of leaking valves. The Agency believes that the equipment leak requirements included in today's final rule greatly reduce the administrative burden associated with LDAR recordkeeping and reporting, and at the same time, result in a significant reduction in emissions.

F. Pollution Prevention Alternative

Many comments were received on the proposed pollution prevention alternative, primarily relating to the proposed restrictions to the use of this alternative and the lack of specific recordkeeping and reporting requirements. The following sections summarize the commenters' concerns regarding the proposed pollution prevention alternative, EPA's response to these concerns, and subsequent changes made in today's final rule.

1. Restrictions on the Pollution Prevention (P2) Alternative

At proposal, processes emitting HAP that are generated in the process were perceived by commenters as being prohibited from using the pollution prevention alternative. Many commenters stated that processes that generate HAP should be allowed to use the P2 alternative as long as these quantities were included in the analysis. These commenters also recommended that the rule provide a de minimis HAP

generation cutoff below which facilities could use the P2 alternative. The EPA agrees with the commenters that PMPU's that generate HAP emissions should be eligible for the P2 standard, provided the HAP emissions generated by the PMPU are controlled to the required levels. Therefore, today's final rule clarifies that processes that generate HAP can use the P2 alternative, provided that the HAP emissions generated in the PMPU are controlled to the required levels for storage tanks, process vents, wastewater and equipment leaks in §§ 63.1253 through 63.1256 of today's final, and the remaining requirements of the P2 alternative are met. Because the final rule requires sources to account for HAP generated in the process, a de minimis HAP generation cutoff is not needed.

No increase in the production-indexed VOC consumption factor was allowed as the result of compliance with the P2 alternative at proposal. One commenter stated that the stipulation in the P2 alternative that does not allow for an increase in the VOC consumption factor as a result of a decrease in use of HAP is unfair. According to the commenter, this restriction will eliminate many solvent replacement projects. The example that the commenter used was a 100 percent reduction in the use of methylene chloride (a non-VOC HAP) by replacing this solvent with a water-based solvent that contains trace amounts of some VOC. This trace

amount of VOC would result in an increase in the VOC consumption factor. The commenter further explained that HAP solvents generally tend to have more aggressive solvent properties than non-HAP, and thus, when replacing a HAP solvent with a non-HAP solvent, the result is generally lower yields, more extensive processing, or higher quantities of solvent used. The commenter suggested that an upper limit could be set on the increase in VOC consumption, and gave a "conservative" limit of two times the baseline production-indexed VOC consumption factor.

In developing the pollution prevention alternative, EPA's intention was to recognize those processes that have reduced or will reduce the amount of HAP solvents used in the manufacture of pharmaceutical products as viable alternatives to add-on controls. By preventing affected sources from increasing the production-indexed VOC consumption factor, EPA intended to prevent solvent substitutions that merely swapped HAP for VOC. After reviewing the proposed pollution prevention standards in light of commenters concerns, EPA realized that the proposed standards gave an unfair advantage to affected sources that use VOC-HAP solvents as opposed to non-VOC HAP solvents. As proposed, the rule did not allow affected sources using non-VOC HAP solvents to switch to low-VOC solvents and still qualify under the pollution prevention alternative because

of the automatic increase in the production-indexed VOC consumption factor. However, affected sources that use VOC-HAP solvents could switch to low-VOC solvents as long as the production-indexed VOC consumption factor did not increase. The EPA's intention in the final rule is that pollution prevention be accomplished through reductions in solvent usage as opposed to solvent substitution. However, the EPA realized that the proposed rule gave un unfair advantage to sources using VOC-HAP solvents as opposed to non-HAP solvents because the rule did not allow affected sources using non-VOC HAP solvents to switch to VOC solvents and still qualify under the pollution prevention alternative. After consideration of this concern, EPA changed the final rule to require an equivalent reduction in the production-indexed VOC consumption factor, if the reduction in the production-indexed HAP consumption factor is achieved by reducing a HAP that is also a VOC. If the reduction in the production-indexed HAP consumption factor is achieved by reducing HAP that is not VOC, the consumption-indexed VOC factor may not be increased. In making these changes to the final rule, EPA essentially eliminated the possibility of receiving credit, through the pollution prevention alternative, for substituting VOC for HAP.

For example, a given PMPU has established its baseline production-indexed consumption factors of 10 kg/kg HAP and

20 kg/kg VOC. The 10 kg/kg HAP factor is made up of 4 kg/kg methanol and 6 kg/kg methylene chloride. The 20 kg/kg VOC factor is made up of 16 kg/kg ethanol and 4 kg/kg methanol. In order to comply with the P2 alternative, the owner/operator would be required to reduce their 10 kg/kg HAP factor to 2.5 kg/kg. This could be accomplished in a number of ways. Even if all the methanol were eliminated, a reduction of 3.5 kg/kg methylene chloride would still be required to yield 2.5 kg/kg. In this case, the production-indexed VOC consumption factor would also be decreased by the 4 kg/kg MeOH to 16 kg/kg VOC; however, no additional reductions of the ethanol would be required.

Today's final rule also changes the time period over which the baseline production-indexed HAP and VOC consumption factors are determined. At proposal, baseline production indexed consumption factors were determined based on the average values for the first full year of operation (or the first year for which data are available). The final rule requires that the baseline production-indexed HAP and VOC consumption factors be determined based on consumption and production values that are averaged over the time period from startup of the process until the present time (assuming the process has been in operation at least 1 full year), or the first 3 years of operation, whichever is the lesser time period. The changes to the baseline averaging period were

made to ensure the baseline production indexed HAP consumption factor reflected normal production.

Another restriction on the pollution prevention alternative that many commenters wanted removed was the exclusion of control devices that recycle material back to the process. A number of commenters stated that the proposed restrictions on the P2 alternative would exclude multiproduct (nondedicated) processes due to strict FDA and quality control restrictions on cross-contamination, which oppose attempts to reduce the amount of solvent consumed per kilogram of product. For this reason, the commenters suggested that the P2 alternative be modified to give multiple-product facilities greater opportunity to make use of this alternative. The specific modification suggested by the commenters includes allowing solvent that is "returned to the economy" to be considered as an alternative for multiproduct processes. The commenters noted that, for implementation purposes, the interested party (first user of the solvent) would need to demonstrate that the required fraction of solvent was transferred to another (second) user as a raw material, to be used as is, so that the second user will purchase that much less solvent. Under this approach, the consumption of HAP would be equivalent to the amount purchased minus the amount sold. Similarly, two commenters suggested that the P2 alternative should be revised to allow

credit for in-process recycling in the calculation of HAP reduction from a process. Although EPA recognizes that multiple-product facilities may not be able to take advantage of the pollution prevention alternative, the type of program whereby one entity certifies the nature and amount of the recovered solvent usage by another entity would be difficult and burdensome to implement, and would require tracking and verifying the usage of the recovered solvent at the second entity. Also, when the recovered solvent is sold to the second entity, the first entity does not achieve any real emission reduction (i.e., reduction in solvent usage), but instead, takes credit for the assumed emission reduction that would occur at the second entity. Also, the second entity may not be a pharmaceutical manufacturing facility which would result in emission reductions being moved across source categories. For these reasons, the final rule does not allow credit for sale of recovered solvents in the P2 standard. Also, EPA disagrees with the commenters that suggest credits be given for in-process recycling because giving a source "credit" for in-process recycling would result in "double-counting" of the emission reduction. By recycling solvents, the owner or operator already has reduced the amount of solvent entering the process (i.e., the more that is recycled, the less that is purchased), so further credits due to recycling are not necessary. For the

reasons given above, the restrictions on solvent recycling in the proposed rule remain unchanged in today's final rule.

2. P2 Demonstration Summary

The proposed rule in § 63.1255(a)(4) would have required sources that comply with the P2 alternative to maintain records of rolling average values of kg HAP/kg production and kg VOC/kg production. The proposed rule also specified how production- indexed HAP and VOC consumption factors should be calculated (i.e., by dividing annual consumption of total HAP or VOC by the annual production rate, per process) but did not require the owner or operator to explain how the reductions in production-indexed HAP consumption factors are achieved. Several commenters stated that EPA should develop data requirements necessary to substantiate compliance with the pollution prevention alternative. Two commenters suggested that the final rule require facilities to submit a "P2 Demonstration Summary" that briefly describes the pollution prevention methods that were used to achieve the reduction in HAP consumption. The commenters stated that information on the facility's P2 activities was necessary to verify that (1) the HAP consumption data are directly related, on a per process basis, to each process that is complying with the P2 alternative; and (2) the reduction in HAP consumption was achieved via pollution prevention methods that meet the Agency's

definition of pollution prevention. These commenters also noted that, in order to provide adequate incentive for facilities to choose the pollution prevention alternative, the EPA should ensure that data requirements are reasonable and protect confidential chemical formulation data. In response to the above comments, today's final rule requires owners and operators seeking to comply with the P2 alternative to submit a P2 Demonstration Summary that describes how the P2 alternative will be applied at their facilities. The P2 Demonstration Summary must be included in the facility's Precompliance Report, which is submitted 6 months prior to the compliance date. The minimum requirements of the P2 Demonstration Summary are listed in § 63.1257(f) of today's final rule. These data requirements include descriptions of how each facility measures and records HAP consumption and pharmaceutical product production on a daily, monthly, and annual basis, and appropriate documentation such as operator log sheets, copies of daily, monthly, and annual inventories of materials and products, shipment and purchase records, tank-specific charts for converting tank-level measurements to volume (e.g., gallons) of HAP or product, and temperature/density charts for converting tank volume measurements into weight measurements. Also, if a facility complying with the P2 standard uses the same HAP in more than one process, the owner or

operator will be required to modify existing methods of tracking HAP consumption at the plant, if necessary, to ensure that HAP consumption can be measured for each PMPU, as opposed to facility-wide.

G. Alternative Standard

Commenters requested that EPA consider an alternative standard for facilities that treat HAP emissions with add-on control devices. Industry commenters stated that an alternative standard would be especially useful for facilities that use a common control device to treat aggregated emission streams. The commenters further stated the use of common dedicated control systems should be encouraged rather than discouraged for the following reasons: (1) the use of common controls will ultimately result in a greater emission reduction because processes that are not required to reduce emissions under the rule would be controlled as well; (2) the use of common controls may facilitate the streamlining of monitoring, performance testing, and recordkeeping requirements and as a result reduce the resource burdens on both industry and the enforcement agencies; (3) the use of common controls may make it easier to assure and assess compliance; and (4) common controls may ultimately be more energy-efficient and result in lower emissions of secondary pollutants since fewer control devices will be employed.

The Agency agrees with the commenters and decided for the above reasons to include an alternative standard for storage tanks and process vents that are equipped with add-on control devices in §§ 63.1253(d) and 63.1254(c), respectively. The Agency also agrees with the commenters' belief that there will be a number of facilities and State regulators that will benefit from a regulatory alternative that encourages aggregating and treating emissions with a state-of-the-art common control device. The alternative standard included in the final rule can be applied to individual process vents or storage tanks that have emissions that are controlled with add-on control devices or to storage tanks and/or process vents that are manifolded together prior to treatment in an end-of-line control device (or series of devices). The control device (or last control device in a series) must achieve an outlet, undiluted TOC concentration of 20 ppmv or less, as methane, or calibrated based on the predominant HAP. The control device must also achieve an outlet concentration of 20 ppmv or less hydrogen halides and halogens. The EPA considers this level of emissions the practical level of control for the technologies on which the standard is based. The requirement to correct for 3% O2 if supplemental combustion air is used is currently under review. This requirement may be revised at a later time.

To simplify applicability of the alternative, all process vent and storage tank emissions that are manifolded to a common control device are considered as one regulated entity under the alternative standard. Nonmanifolded vents are regulated under the rule as otherwise specified without taking credit for the manifolded portion of the process.

H. Testing and Compliance Demonstrations

1. Worst-Case Conditions for Testing

Extensive comments were received on the provisions for absolute or hypothetical worst-case testing contained in the proposed rule. Many commenters stated that the provisions are not workable, especially in batch facilities where multiple streams are routed to common control devices. In these situations, owners and operators might be required to cease production in order to simulate a hypothetical worst-case test for a given device, or would have to artificially affect production in order to align emission events for testing that would meet absolute worst-case conditions. Commenters emphasized that, in both situations, there are safety concerns associated with generating such conditions, as well as practical concerns.

One safety concern raised by the commenters related to both absolute and hypothetical worst-case testing is that the manifold systems designed to carry emission streams to control devices may not be sized to handle the absolute

worst-case situation, which could lead to potentially explosive situations during absolute and hypothetical worst-case testing. Many commenters stated that sources often design and install manifold systems at a lower capacity than that of the control device itself to prevent such explosion potential.

The most common practical concern expressed was that the prediction of when worst-case conditions would be occurring would be very difficult, although many commenters stated that calculating the potential maximum inlet loading scenario for a control device used to control emissions from multiple batch processing vessels would be a difficult, but manageable, task. Many commenters suggested that fluctuations related to processing, including sudden changes in temperatures or operator, could shift the timing of emission events and render any predictions about the timing of specific events invalid. The commenters believe that, for devices controlling multiple streams from moderately complex facilities, absolute worst-case test conditions might never occur within the life of the facility, nor could they reasonably be predicted. Additionally, one commenter stated that an owner or operator might encounter difficulty in proving to a compliance inspector that the conditions of a test were, indeed, run at absolute worst case.

A practical concern with hypothetical worst case conditions raised by the commenters is that testing cannot be performed while an actual batch is being produced. Based on the commenters' past experiences, testing in some cases could result in a process shutdown for 2 weeks, resulting in serious production losses.

One commenter also stated that representative worst case will also result in timing uncertainties similar to those of the absolute worst-case situation, especially when the device is controlling a single process with numerous emission episodes.

For normal testing conditions, commenters believe that the restriction to operate within conditions that existed during the test should be dropped. They stated that, because the proposed standards include an annual compliance period, the commenters argued that the control device will constantly see variably challenging conditions and therefore, should be allowed to operate under conditions that are outside the range of conditions encountered during testing. In order to alleviate the EPA's concerns that a test under normal conditions may not indicate a control device's performance under more challenging conditions, one commenter suggested that an additional requirement to provide a design evaluation under more challenging conditions be added. Many commenters also suggested that

representative worst case should be revised to include all control devices, and should not be restricted to “the level for which it was designed.” Additionally, one commenter believes that EPA did not mean to impose this limit on representative testing conditions and would like EPA to make the appropriate language changes to reflect their intent. Lastly, several commenters expressed approval of testing under worst-case conditions, but would like the conditions to be more clearly defined.

The Agency’s intent in requiring testing under worst case conditions is to document the reduction efficiency of the control device under its most challenging conditions. Subsequent to the initial compliance test, continuous monitoring of operating parameters established during the initial test is a reasonable measure of continuous compliance with the efficiency requirement under all conditions. Presumably, the control device should function as well or better under conditions that are not as challenging.

Many of the comments regarding worst-case testing conditions are related to the restrictive language defining the worst case challenge and the difficulty associated with developing a time-dependent emissions profile to identify the appropriate test period. In an effort to provide more flexibility to owners and operators regarding the identification of the proper testing conditions, EPA has

redefined the worst case “challenge” to include challenging conditions that are not based on high HAP load. These conditions include cases where efficiencies are dependent on other characteristics of emission streams, including the characteristics of components and the operating principles of the devices. For example, in situations in which non-HAP VOC’s are present, where the efficiency of a device is most challenged by dilute steam characteristics or where specific characteristics of the compounds create limitations on control efficiency. In sizing and estimating the regeneration requirement for a carbon adsorber, for example, all material in the emission stream entering the unit must be considered in estimating bed capacity. Likewise, a limiting factor in scrubber efficiency is the solubility or reactivity of components in the scrubbing liquor. These considerations must be made at the time of evaluation of the device for compliance with the rule.

For worst-case challenges that are based on loading of HAP, EPA has also expanded the language describing the development of the emission profile. The emissions profile can be developed based on the actual processing conditions at the facility, as proposed, in which all emission events that can contribute to the control device are identified and considered to determine the highest hourly HAP load from all events that can occur at the same time. However, in the

final rule, other options for the emissions profile have been developed that consider the facility's limitations based on equipment or conveyance and capture systems. Owners and operators can develop emission profiles based on equipment, in which the highest hourly HAP-producing emission streams that possibly could enter the control device, considering the facility's available equipment and HAP materials, are identified as appropriate testing conditions. Also, owners and operators have the option to develop emission profiles based on limitations of the control device or conveyance system. For example, many manifolds are limited in flows and concentration limits by fans and LEL monitors. Conducting performance tests based on conditions approaching these limits is also an option provided in the rule.

The expanded language on emission profiles eliminates the need for allowing owners and operators to test at conditions that are less than the worst-case challenge. Therefore, language referring to testing under "representative" and "normal" conditions was deleted from the batch testing provisions. Additionally, the added flexibility associated describing worst case may alleviate commenter's concerns regarding loss of production time.

2. Expedited Test Methods

Many commenters stated that the test methods referenced in the proposal under § 63.1253(b)(1) through (6) will require modification, because the methods were developed for continuous processes. Based on the commenters' past experience, obtaining approval for modifications to test methods often takes 6 to 12 months. Therefore, the industry commenters would like for EPA to consider adding explicit language in the rule allowing for the use of alternative test methods and providing some mechanism for expedited approval.

Specific suggestions from the above commenters for expediting approval were to eliminate EPA's validation Method 301 in favor of a less burdensome method and to explicitly state that approval of minor modifications do not require Method 301 validation, or that approval of alternative test methods should not trigger the need for a title V permit revision.

In response to the above comments, the Agency believes that the provisions in the final rule that require a site-specific test plan be submitted prior to any testing suffice in providing a mechanism for the presentation of, and approval of, proposed modifications to EPA test methods. In general, Method 301 should be used as a validation method for completely new and different testing procedures and instruments that have not previously been reviewed by EPA.

It is not the Agency’s intent to require the use of Method 301 for minor modifications to test methods such as the relocation of sampling probes.

3. Use of Method 25A

One commenter stated that Method 25A should be used only after an accurate response factor has been determined. The final rule specifies the following test methods:

1. Method 18 for control efficiency in all situations.

2. Method 25 for control efficiency determination in combustion devices.

3. Method 25A for the 20 ppmv outlet TOC concentration standard.

4. Method 25A in control efficiency determinations in the situations described in the introductory paragraphs of Part 60, Appendix A, Method 25 (when direct measurement by FID is appropriate).

The importance of calibrating a FID reading obtained using Method 25A with respect to a certain compound (adjustment by response factor) depends on how the Method will be used to demonstrate compliance with the standard. In general, the EPA believes that an accurate response factor is necessary in cases where Method 25A is used to demonstrate control efficiency across a device where the composition of the stream may change, or in situations where multiple components, including non-HAP VOC's, are present.

Because the relative proportion of organic compounds may change across the control device, appropriate response factors are needed to accurately quantify TOC at the inlet and outlet of a control device. In addition, the final rule allows owners and operators the opportunity to demonstrate compliance at the outlet of a control device by measuring 20 ppmv TOC or less. The EPA has allowed owners and operators to calibrate the FID using methane or the predominant HAP expected in the emission stream. The use of methane as a calibration gas for the 20 ppmv TOC alternative standard is based on the response factor of methane because it is similar to response factors of HAP that are predominant in this industry, such as methylene chloride and methanol. The EPA intends with this requirement to minimize the burden of recalibration for various HAP constituents that may actually change over a given period of time.

4. Emission Profiles

Many commenters requested clarification of the methodology for developing an emissions profile, which was contained in § 63.1253(b)(iii) of the proposed rule. The commenters stated that the definition of emissions profile implies that sources must prepare a graph of HAP emissions versus time. However, because EPA included the language "the average hourly HAP loading rate may be calculated by first dividing the HAP emissions from each episode by the

duration of each episode, in hours, and selecting the highest average hourly block average", the commenters thought that EPA's intent was not to profile emissions versus time, but rather to simply list each batch episode and the average hourly HAP emissions loading from each episode. Additionally, some commenters stated that the emission profile method seemed very complicated, and that personnel with operating experience can quickly determine the worst-case conditions for a control device without producing the extensive information required by the emissions profile. One commenter suggested changing the language of § 63.1253(b)(7)(iii) (A) by eliminating the phase "must include," so that sources can have the option of discussing an alternative means of determining appropriate test conditions with the permitting authority.

The Agency's intent, when requiring the development of an emissions profile, is to determine the maximum HAP loading to a control device over time. Therefore, the rule requires that the emissions to the device be evaluated by plotting HAP emissions versus time. The EPA has not, in the final rule, changed the requirements for developing the emissions profile, although EPA did clarify the exact language in the final rule to address the commenter's concerns about the clarity of the requirement.

Additionally, two other methods for developing the emission profile were provided in the final rule.

I. Equations

1. Use of Equations in 1978 CTG

As part of the procedure to demonstrate compliance with the emission reduction standard for process vents, the final rule requires the owner or operator to determine uncontrolled emissions from each vent. Equations to calculate emissions from certain unit operations are provided in the rule. Numerous commenters requested that the rule also allow the use of similar equations for the same unit operations that are presented in the 1978 CTG. The commenters stated that although the two procedures give different results, they are based on the same fundamental principles and neither gives better results. The commenters provided the following additional reasons for allowing use of the equations from the 1978 CTG: (1) the MACT floor was based on data from the industry, which were estimated using the procedures in the 1978 CTG, (2) sources are already using the procedures in the 1978 CTG to comply with other regulatory programs and would incur significant costs to invest in a program and data systems to develop and maintain a second method for estimating emissions, (3) maintaining two sets of emission estimates would make State review and compliance efforts complex and confusing, possibly leading

to compliance actions for perceived violations of one estimate but not the other, and (4) the emission estimation equations in the rule are based on the 1994 ACT, which has not undergone public review and comment.

The EPA reevaluated the procedures for calculating uncontrolled emissions and concluded that except for two situations, the equations in both the 1978 CTG and the 1994 ACT documents give acceptable estimates of emissions for the purposes of this rule. Therefore, both sets of equations, except as noted below, are included in the final rule for existing sources. The two situations for which emission estimation procedures in the 1978 CTG are not acceptable for this rule are: (1) purging with streams that have high flow rates and (2) heating when the final temperature is higher than 10 K below the boiling point. The EPA believes this change mitigates the commenters concerns because the two situations where the 1978 CTG procedures are not allowed affect a small number of streams. Owners and operators will have to redo calculations for existing processes under these two conditions. In addition, the owner or operator will have to calculate uncontrolled emissions for those events that the owners/operators have only controlled emission estimates. This is because the 1978 CTG uses condenser temperature instead of vessel temperature. Details about

the equations for purging and heating are provided in sections VI.I.2.b and VI.I.3.

2. Procedures to Estimate Emissions from Purging

a. Equation. The equation for purging was changed in the final rule because the term that accounts for the increase in flow rate due to the volatilization of HAP was inadvertently left out of the equation in the proposed rule (i.e., the purge flow rate needs to be multiplied by the ratio of the total pressure to the partial pressure of noncondensables at saturation). The revised equation is identical to the equation in the 1994 ACT and gives the same results as the equation in the 1978 CTG as long as the total pressure is equal to 760 mmHg.

b. Saturation level for large purge streams. The rule requires an owner or operator to assume a purge stream greater than 100 scfm is 25 percent saturated. One commenter believes the assumption that the vapor phase is 25 percent saturated rather than 100 percent saturated is merely a different assumption and is not based on better information. The commenter also stated that assuming streams are 100 percent saturated is more conservative because it will overestimate emissions, whereas the 25 percent assumption will sometimes overestimate and sometimes underestimate emissions.

The assumptions that purge streams with flow rates less than or equal to 100 scfm are 100 percent saturated, and that purge streams with flow rates greater than 100 scfm are 25 percent saturated, are based on modeling analyses that are described in the 1994 ACT. In the 1994 ACT, the mass transfer (of toluene) from the liquid to the purge stream was estimated using various correlations and a range of design and operating parameters. The correlations showed the purge streams, especially purge streams with high flow rates, were well below saturation for all but the most agitated vessels or vessels with very shallow head space. Assuming these large streams are completely saturated would result in significantly overestimated uncontrolled emissions.

Overestimating uncontrolled emissions leads to at least two problems. First, for a condenser, overestimating uncontrolled emissions means the control efficiency of the condenser will be overstated (and the condenser will operate at a higher temperature than is actually needed to meet the standard). A second problem with overestimating the uncontrolled emissions is that even if the control efficiency is being met (say with an incinerator), the quantity of emissions reductions would also be overestimated, which, if this stream were used in emissions averaging, would result in overestimation of credits. To mitigate these problems, EPA

reviewed the results of the modeling analyses and selected values that while still conservative greatly reduce the potential amount of overestimation. The correlations showed that under all types of conditions, the degree of saturation declines rapidly with increases in purge flow rate up to about 100 scfm, and then nearly levels off; the “knee” of the curve was at about 100 scfm for every scenario. For all modeled scenarios, purge flow rates greater than 100 scfm were always less than 25 percent of saturation. Based on these results, the EPA believes that assuming purge streams with flow rates greater than 100 scfm are 25 percent saturated rather than 100 percent saturated results in a better estimate of emissions, more accurate operating parameters, and reasonable credits for emissions averaging. Thus, the requirement to assume purge streams with flow rates greater than 100 scfm are 25 percent saturated was retained in the final rule; but an owner or operator also may conduct an engineering assessment to show that another value is more appropriate.

3. Procedures to Estimate Emissions from Heating

a. Heatup temperature within 50 K of boiling. When the contents of a vessel are heated to a temperature within 50 K of boiling, the proposed rule would require the owner or operator to calculate emissions in increments. One increment covered the range from the initial vessel

temperature to the temperature 50 K below the boiling point. The procedure then required estimates for each 5 K temperature range up to the final heatup temperature. One commenter believes calculating over 5 K increments is overly conservative. Other commenters believe the approach is an error because it differs from the approach in the 1994 ACT.

As noted in section VI.I.1, EPA is changing the rule to include the equations from the 1978 CTG and the 1994 ACT as well as the approach in the proposed rule for most heatup conditions at existing sources. In response to industry concerns, the EPA is also reducing the temperature cutoff from 50 to 10 K below the boiling point. The concept of a cap is retained because the procedures in the 1978 CTG and the 1994 ACT can greatly overestimate emissions when the final heatup temperature is close to the boiling point. The equation in the 1978 CTG estimates emissions assuming equilibrium at the temperature of a receiver (i.e., the equation uses a ratio of the condensables partial pressure to the noncondensables partial pressure at equilibrium). This procedure does not specify what equilibrium conditions should be used in the absence of a condenser. If the equilibrium partial pressures at the final heatup temperature are used, the equation overestimates emissions. The overestimate is most significant when the final heatup temperature is close to the boiling point because the

partial pressures ratio (condensables to noncondensables) increases exponentially with increasing temperature, and goes to infinity as the temperature approaches the boiling point. Using the average of the ratios at the initial and final temperatures, as is done in the 1994 ACT, also can overestimate emissions. The EPA believes calculating emissions over the 5 K increments when the final heatup temperature is above the temperature 10 K below the boiling point is a reasonable compromise between the accuracy of the estimate and the effort needed to perform the calculation.

b. Emissions From Process Condenser. Under the proposed rule, if the contents of a vessel are heated to the boiling point and the vessel operates with a process condenser, the emissions would be calculated using both the heatup and displacement equations. One commenter noted that this procedure results in negative emissions. The EPA reevaluated this equation and determined that this result occurs only if the process condenser operates at a temperature lower than the initial temperature of the vessel. To correct this problem, the final rule states that either the heatup procedure in the 1978 CTG or a variation of this procedure is to be used. The variation allows the owner or operator to use a vapor-liquid equilibrium relationship other than Raoult’s law and to use the actual system pressure rather than assuming the system is at atmospheric

pressure. Both procedures are also applicable when the condenser temperature is higher than the initial temperature of the vessel.

4. Vapor-Liquid Equilibrium Relationships for Multicomponent Systems

To estimate emissions, the rule specifies that owners and operators assume one of four vapor-liquid equilibrium (VLE) relationships apply, depending on the system conditions. These relationships are: (1) Raoult's law, (2) Henry's law, (3) a VLE relationship based on the use of activity coefficients (obtained experimentally or from models) to correct for nonideality in the liquid phase, and (4) the assumption that components of the system behave independently so that the sum of all HAP vapor pressures is equal to the total HAP partial pressure. Once the applicable VLE relationship is established, the HAP partial pressure(s) can be determined and used in the applicable equation to estimate the HAP emissions.

Two commenters expressed concern about some of the VLE relationships that the rule requires for estimating emissions from multicomponent systems. The commenters concur with EPA that Raoult's law is appropriate for miscible systems. The commenters also acknowledged that use of Henry's law is generally more accurate that Raoult's law in predicting vapor mole fraction for mixtures below the

solubility limit, but they stated that this approach is excessively difficult and unworkable because Henry's law constants are not available for many of the solvents and reagents used in the pharmaceuticals industry. Therefore, the commenters would prefer to use Raoult's law for these mixtures. For multicomponent systems in which the compounds are not miscible or are only partially miscible, the commenters opposed the use of equilibrium relationships based on activity coefficients because developing activity coefficients is burdensome. As an alternative, the commenters recommended using an approach in which each liquid phase is treated independently, and emissions from each phase are calculated separately.

The final rule clarifies EPA's intent regarding the use of vapor-liquid equilibrium relationships. If the components are miscible in one another, Raoult's law may be used when it is applicable. However, if a miscible solution is not well characterized by Raoult's law, activity coefficients must be used. For dilute aqueous mixtures, Henry's law must be used. The EPA rejects the commenter's argument to use Raoult's law due to the lack of Henry's law constants; Table I of appendix C in 40 CFR 63 contains Henry's law constants at 25°C and 100°C for 125 of the most common organic HAP compounds. For HAP compounds that are not on the list, the owner or operator must estimate the

Henry's law constant. For systems with multiple liquid phases, the owner or operator may either use activity coefficients or, as suggested by the commenter, assume the components behave independently and assume the HAP vapor pressures and partial pressures are equal.

5. Emission Estimation Equations Versus Engineering Assessments

The rule lists two conditions under which an owner or operator may conduct an engineering assessment to show that equations in the rule are not appropriate: (1) if available test data and the results of calculations using an equation differ by more than 20 percent and (2) if the owner or operator can demonstrate through any other means that the emission estimation equations are not appropriate for a given batch emissions episode. Several commenters stated that both conditions should be deleted from the rule. The commenters rationale for deleting the conditions shows the language in the proposed rule did not convey EPA's intent. As a result, the conditions are rewritten in the final rule for clarity, and additional clarification is provided in the following paragraphs of today's notice.

Batch emission episodes may be due to a unit operation that is described by an equation in the rule or to a unit operation that is not described by an equation in the rule. Estimating emissions using the applicable equation is always

the standard approach for emissions episodes that are covered by an equation. However, an owner or operator also always has the opportunity to conduct an engineering assessment to demonstrate and get approval to use another emission estimation technique. The intent of the first condition is to indicate that an owner or operator could include such a discrepancy between test data and calculations in an engineering assessment and it would be considered evidence that the equation is not appropriate (provided, of course, that the permitting authority agrees that the test data were obtained under "representative conditions"). The purpose of the second condition is to indicate that other information may also be used in the design evaluation as evidence that an equation is not appropriate. Again, the permitting authority would have to approve the use of any proposed alternative to the equation.

The conditions have nothing to do with estimating emissions for batch emissions episodes from unit operations that are not described by equations in the rule. For such emissions episodes, an owner or operator would be required to conduct an engineering assessment to show how emissions will be estimated.

6. Calculation of Controlled Emissions

Two commenters stated that the rule should allow the use of techniques in the 1978 CTG to calculate controlled

emissions from a condenser. The commenters stated that the procedures in the proposed rule cannot be used because they specify the use of system temperature, whereas the correct technique, which is used in the 1978 CTG, is to use the exit gas temperature from the condenser. One commenter also stated that even when the equations in the rule and the 1978 CTG are identical, "implementation differences" cause the controlled emissions estimates to differ. To address the commenters' concerns, the final rule specifies both the applicable equation and any changes to the temperature or volume that are needed for calculating controlled emissions.

J. Monitoring Requirements

Many commenters objected to the use of monitoring parameters for the determination of a source's compliance status on a continuous basis. Their central issue, for many emission streams controlled in this industry (e.g., batch, nondedicated, possibly manifolded together and routed to common control), is that an exceedance of a parameter level, as measured on 15-minute intervals and averaged over a 24-hour basis, may not necessarily constitute a violation of the 93 percent control requirement for the process for the following reasons:

1. If the parameter is conservative, the device will operate above the required efficiency;

2. The loading on the control device may be less than the assumed loading used to set the parameter, so the device provides adequate control even though the parameter has not been attained;

3. The actual compounds in the emission streams may be easier to treat than those used to set the parameter; and

4. The excursion may occur when there are little or no HAP emissions from the process routed to the device.

The EPA had solicited comment on this issue, and at that time, had questioned why the industry couldn't set multiple parametric levels for control devices to account for different operating scenarios. The commenters countered that, especially in the case of manifolded, end-of-line devices, it is not possible to predict with precision what conditions will exist at any point in time. Rather than establishing, up-front, a complex "grid" of parameters that will serve all potential combinations of operating scenarios, they would want to set conservative parametric levels as a screening mechanism for determining whether or not emission limits might have been exceeded, with an option to evaluate actual parameter excursions on a case-by-case basis after exceedances had occurred to determine whether an emission limit was actually exceeded.

The commenters recommended that the rule provide that a parameter exceedance must be reported to the permitting

authority, with the opportunity to rebut the presumption that the emission limit(s) have been exceeded. Other commenters suggested that sources be treated in a manner consistent with the Compliance Assurance Monitoring (CAM) rule, which provides only that an excursion of a monitored parameter is an indication that an emission standard may have been exceeded, but makes no automatic finding of a violation of that emission standard.

In general, EPA recognizes two basic approaches to assuring that control devices used by the owner or operator to achieve compliance are properly operated and maintained so that the owner or operator continues to achieve compliance with applicable requirements. One method is to establish monitoring as a method for directly determining continuous compliance with the applicable requirements. The Agency has adopted this approach in part 63 standards, and is committed to following this approach whenever appropriate in future rulemakings. Another approach is to establish monitoring for the purposes of documenting continued operation of the control devices that are designed to provide a reasonable assurance of compliance, indicating excursion from these ranges, and correcting problems creating excursions. This second approach is outlined in the CAM rule, which applies to sources that are not currently subject to part 63 standards.

When determining appropriate monitoring options, EPA considers the availability and feasibility of the following monitoring strategies in a “top-down” fashion: (1) CEMS for the actual HAP emitted, (2) CEMS for HAP surrogates, (3) monitoring operating parameters, and (4) work practice standards. In evaluating the use of CEMS in this standard, monitoring of individual HAP species was not found to be reasonable or technically feasible for many streams. However, in the case of continuous monitoring of surrogates, continuous TOC monitoring is considered a more viable monitoring option and is provided for some instances in the rule. (See discussion on alternative standard and on monitoring for carbon bed systems.) Monitoring of control device operating parameters is considered appropriate for many other emission sources, and therefore, most of the other monitoring options provided in the final rule are based on parametric monitoring.

The EPA has considered the commenters’ argument that an exceedance of a monitoring parameter is not necessarily an exceedance of an emission limit, especially as described in the generic situations provided above. In the first three situations, EPA believes that as long as the source is given the flexibility to select operating parameters, including the option retained from the proposed rule to allow the owner or operator to set multiple parameter levels for

different operating conditions, then the burden is on the source to remain within the parameter or parameter(s).

To address the potential disparity between parameter limit exceedances and emission limit exceedances, the final rule contains two different types of continuous compliance violations. Where a source is using a CEMS to monitor compliance with the 20 ppmv alternative standard, an exceedance is defined as a violation of the emission limit. Similarly, because the exit gas temperature of a condenser is so closely correlated with emissions, a condenser temperature exceedance is considered a violation of the emission limit. Exceedances of other types of parameter limits are defined as violations of an operating limit, rather than violations of the emission limit.

In response to industry's preference to evaluate parameter levels after an exceedance of a conservative parameter level to determine whether an emission limit was exceeded (thereby eliminating the need for a complex grid of preset parameter levels), EPA believes that the establishment of compliance levels <u>prior</u> to operation of the device or process is imperative; otherwise, the constant opportunity for rebutting a violation of the standard would render the standard unenforceable. While EPA is sensitive to industry's need to minimize its compliance burden, EPA believes that the burden placed on State agencies to

consider the amount of information that the rebuttable presumption option would encourage is not reasonable.

In response to the fourth generic situation described by industry, EPA has provided in the final rule, clarification of situations (no flow) when exceedances of preset parameters would not constitute a violation of the standard.

For reasons described above, EPA rejects the assertion that the parametric levels should not be used as a direct indicator of compliance. The EPA believes that conditions in the proposed rule which have been retained in the final rule including options for setting parameters, coupled with clarifying the averaging times for compliance determinations and establishing valid data criteria for monitored parameters should address concerns of commenters, while retaining the enforceability of the standard. The final rule provides options for presetting multiple parameter levels to account for variation in batch emission stream characteristics within emission sources (as proposed), and to account for variability in combined stream characteristics in manifolds.

The final rule provides owners and operators with the option of setting averaging times based on either a “block” of time suitable for the expected variations of emission stream characteristics from a batch process (determined by

the owner or operator, with some restrictions), or a 24-hour basis (as proposed).

The final rule also provides owners and operators with an opportunity to verify compliance based on a review of operating logs during periods of exceedances. Exceedances will not constitute violations of subpart GGG during periods when a parameter has been set based on worst-case conditions, or other conditions that were not representative of the conditions in the device during the exceedance, if the owner or operator has predetermined other levels that ensure compliance with the standards for these representative periods. If predetermined levels were established, the owner or operator can also determine compliance for discrete streams in manifolds by referencing to these limits.

Additionally, monitored data obtained during periods in which no flow to the control device occur should not be considered valid; during such periods, the final rule allows for the exclusion of such data from the daily or block averages. The use of a flowmeter to identify and exclude such periods from compliance average is therefore required in the final rule, if they cannot otherwise be predicted.

K. Recordkeeping and Reporting Requirements

Issues related to the amount and type(s) of recordkeeping and reporting requirements that were included in the proposed rule were raised by commenters representing

both industry and enforcement agencies. The pharmaceutical manufacturing industry involves a wide variety of processes, products, and resulting emissions. In order to demonstrate compliance with the necessary MACT requirements, detailed records are needed to have a reliable, documented record of how the source complied with the regulation. The EPA has made a concerted effort to reduce the recordkeeping require-ments of the final pharmaceutical rule. The EPA recognizes that unnecessary recordkeeping and reporting requirements would burden both the affected source and EPA/State enforcement agencies and will continue to review requirements to identify and implement other possible streamlining measures.

The EPA has reviewed the recordkeeping and reporting requirements required by the proposed rule and has eliminated those areas where duplicative and inapplicable requirements were proposed. Most of these changes involved areas where the referenced General Provision requirements were not directly applicable to this industry. Clarifica-tions and/or additional language have been added to tailor the recordkeeping and reporting requirements to the relevant data needs from pharmaceutical manufacturing operations. Table 1 in today’s final regulation was modified to include a summary column describing the relevant information in each part of the General Provisions, and more information was

added to better relate the requirements of the final rule and those in the General Provisions.

Comments on precompliance reporting were varied depending on the commenter's perspective and experience. Some commenters viewed the precompliance reporting requirements as burdensome and restrictive. One commenter stated that submittal dates for reports and notifications due prior to the compliance date are much too early, unnecessary, and can be counterproductive. Two commenters stated that the Precompliance Report should be due only 3 months prior to the compliance date. Other commenters argued that the "early" due date for the Precompliance Report is valuable because it provides a practical means of ensuring that a source is aware of the upcoming deadline. One of the commenters also stated that the description of test conditions and limits of operation for control devices tested under normal conditions and the corresponding monitoring parameter values should be submitted as part of the Pretest Notification Report rather than with the Precompliance Report. In response, the Agency revised the submittal dates for the precompliance report and the emissions averaging implementation plan to 6 months prior to the compliance date. The Agency believes the final submittal dates and data requirements for the precompliance report are adequate

to provide the enforcement agencies with sufficient time to review the information.

Some commenters also suggested that the use of alternative parameters be included in the precompliance report and that periodic testing be done to correlate actual emission rates to alternative parameters. The EPA response to this issue is addressed in section VI.L of this preamble.

One commenter suggested that sources be required to establish an effective environmental management system to eliminate much of the paperwork burden associated with the proposed recordkeeping and reporting requirements. The Agency believes an effective environmental management system can be used to comply with all the requirements of the final rule provided the system is based on meeting the MACT requirements in the final rule. Sources are free to submit an alternative compliance plan to the appropriate agency to review/approve in lieu of any or all recordkeeping or reporting requirements.

Commenters also raised issues related to data availability stating that the proposed requirements were unreasonable, impracticable, and more stringent than those for other industries. The Agency does not agree with these comments.

L. Permitting and Compliance Options/Change Management Strategy

1. Proposal Comments Received

In the April 1997 proposal, the EPA solicited comment on the interaction of this standard with the title V operating permits program, implemented at 40 CFR part 70. In addition, the Agency requested comment on an approach which would incorporate by reference the Notification of Compliance Status Report (NOCSR) into a pharmaceutical manufacturing facility's title V permit. The EPA also solicited comment on the types of operational changes that would trigger revision of the operating permit under title V. However, in soliciting comment on these issues, the Agency did not propose to revise part 70 through the establishment or implementation of subpart GGG.

Commenters to the proposed subpart GGG raised several issues with respect to process changes at pharmaceutical facilities, which they claimed would result in a potentially unmanageable title V permit administrative process. The pharmaceutical industry produces a wide range of existing and new and/or improved products primarily through the use of nondedicated equipment operated in a batch production mode. Commenters were fearful that frequent changes in the use of existing equipment as well as the additions of new equipment at pharmaceutical facilities would require frequent revisions to the operating permits for these facilities. These commenters predicted that such permit

revisions would result in delays in implementing process changes and cause significant new administrative burdens on the facility and permitting authority.

The preamble to the proposed rule described the NOCSR as the compliance “blueprint” for implementation of the standard, containing "[a]ll information regarding documentation of the facility's compliance status with regard to the standard. . . ." This information would include "process descriptions, emissions estimates from those processes, control device performance documentation, and continuous compliance demonstration strategies, including monitoring." The EPA solicited comment on whether the NOCSR could be initially incorporated by reference into the title V permit and whether the permit could be revised as necessary through quarterly update reports. The proposal posited that only changes requiring site-specific approval (such as the use of a monitoring parameter that was not identified in the standard) would trigger some significant review action under title V. The Agency expressed the view that this approach would allow enough flexibility for sources to make operational changes as necessary as well as changes to operating and compliance procedures without additional approval, if the changes were straightforward, and would assure that the compliance plan for the facility would always be reasonably current.

Most commenters did not support an ongoing implementation strategy based on permit revision for operational changes, even if it could be streamlined. Several industry commenters strongly reiterated concerns about the potentially huge administrative problems associated with implementing subpart GGG within title V permits.

In particular, PHRMA recommended an approach under which facilities that have been issued a title V permit before subpart GGG is finalized would be required to apply for a minor permit modification (MPM) by the due date for the NOCSR. The suggested MPM application would include: (1) a list of applicable subpart GGG requirements that should be included in the permit itself (including a "menu" of applicable process vent, tank, and wastewater standards); (2) a requirement for the facility to submit a compliance plan that outlines the regulated entities within the affected source (such list should include the identification of regulated processes, process vents, tanks, and wastewater PODs; a determination as to which substantive standard applies to each; and a list of corresponding testing, monitoring, record keeping, and reporting requirements); (3) a requirement for the facility to update the plan when a compliance requirement changes; (4) a requirement to submit the plan to the permitting authority

every 6 months; and (5) a requirement to operate in accordance with the plan. For facilities that have not been issued a title V permit until after subpart GGG is finalized, a facility's initial permit would be issued to include these five items. Facilities that trigger new source MACT would be required to apply for a significant permit modification (SPM) prior to implementing the triggering change. Under this approach, PHRMA believes that a source could make most changes at the affected facility without triggering a title V permit revision, provided the compliance plan was updated to indicate the new regulated entities and/or new requirements that would result from the change, thus avoiding delay while ensuring that the part 70 requirements are satisfied through timely recording of the requirements applicable to the source.

Title V requires operating permits to assure compliance with all applicable requirements at a source, including a section 112 standard such as subpart GGG. An existing source subject to subpart GGG must include in its operating permit by the time of the standard's compliance date -the latest date by which most provisions of the standard would become applicable requirements at existing affected sources- sufficient permit terms and conditions to assure compliance with the standard. If a source's initial title V permit does not include terms to assure compliance with subpart GGG

by the compliance date, the permit must be revised to incorporate the standard not later than 18 months after the standard's promulgation. See CAA section 502(b)(9). This will ensure that subpart GGG is reflected in title V permits for pharmaceutical facilities by the time of the compliance date and as required by statute, since the compliance date for subpart GGG is up to 36 months after the standard's promulgation (see section 63.1250(f)(1). Consistent with section 502(b)(6) of the Act, however, if the standard is promulgated when fewer than 3 years remain on a major source's permit term, a permitting authority's program may reflect the option not to require revisions to the permit to incorporate the standard. The Act permits State programs to require revisions to the permit to incorporate the standard in such instances, however, so any sources with fewer than 3 years remaining on their permits upon the promulgation of today's action, should consult their State permitting program regulations to determine whether revision to their permits is necessary to incorporate subpart GGG.

The EPA does not believe that PHRMA's recommended permitting approach would ensure that operating permits for pharmaceutical facilities assure compliance with subpart GGG by the standard's compliance date and subsequently during the permit term. PHRMA recommends including basic permit content information--such as the identification of regulated

emissions units and activities, and their associated compliance requirements--in an off-permit compliance plan, when such information is appropriately required in the permit. The proposal addressed this point by soliciting comment on the incorporation by reference into the facility's permit of the NOCSR. The EPA believes that it is possible to provide the flexibility sought by pharmaceutical manufacturers while maintaining Congress' intent that the title V permit contain all of the applicable Federal requirements. However, neither the proposal nor today's final rule purports to revise part 70 to accomplish this transfer of permit content from the permit to an off-permit compliance plan, and EPA does not believe that a MACT standard such as this is the appropriate vehicle to accomplish revisions to part 70. A separate rulemaking is currently underway to revise part 70, and features of today's approach may be adopted in that rulemaking.

Moreover, for facilities that have been issued a title V permit before the MACT is promulgated, PHRMA's recommended approach would not meet the requirement that these permits assure compliance with subpart GGG by the standard's compliance date. In addition, the approach would not satisfy section 502(b)(9)'s requirement that such permits be revised not later than 18 months after the promulgation of subpart GGG. PHRMA recommended that

facilities that have been issued a title V permit before the MACT is promulgated be required only to apply for a MPM by the due date for the NOCSR. The due date for the NOCSR under subpart GGG can fall as late as 150 days after the compliance date, see section 63.1260(f), and the compliance date for existing sources is within 3 years after the promulgation date of the standard, see section 63.1250(f)(1). Finally, under section 70.7(e)(2)(iv), a permitting authority may have up to 90 days following receipt of a MPM application to issue an actual MPM reflecting subpart GGG.

Therefore, PHRMA's recommended approach would allow existing sources with title V permits to delay revisions to their permits to incorporate subpart GGG as long as 44 months--36 months plus 5 months plus 3 months--after promulgation of the standard, when section 502(b)(9) requires such revisions to be accomplished not later than 18 months after promulgation of the standard. In addition, of course, PHRMA's approach would not ensure that existing sources subject to subpart GGG have permits that assure compliance with the standard by the time of the standard's compliance date. For these reasons, EPA declines to adopt PHRMA's recommended approach in its entirety. However, as stated above, EPA believes the Agency can meet the

industry’s needs while complying with statutory obligations and Congressional intent.

The EPA agrees that some types of pharmaceutical operational changes may be subject to frequent title V revisions. As a result, the EPA met with industry representatives to clarify industry comments received on the proposal. In response, EPA developed a recommended approach for managing changes involving reconfigurations of existing equipment and the additions of certain new equipment subject to the pharmaceutical MACT through title V permits. This change management strategy in general adopts aspects of both the EPA proposal (e.g., to incorporate the NOCSR into the title V permit) and of industry suggestions for managing change made subsequent to the NOCSR.

2. Description of Recommended Approach

a. General strategy for change management. This notice presents an interpretation of the current regulations at 40 CFR part 70, for purposes of an experimental permitting approach under which title V operating permits may be designed to implement subpart GGG and provide operational flexibility without frequent permit revision. This approach represents EPA’s current views on these issues and, while it may include various statements that permitting authorities or sources may take certain actions, these statements are made pursuant to EPA’s

preliminary interpretations and, thus, are not binding on any party as a matter of law. Only if EPA makes its interpretations final through rulemaking will they be binding as a matter of law. This means that States are not required to follow this approach in implementing subpart GGG through their operating permit programs, and EPA will fully and fairly consider all comments and petitions calling upon the Agency to object to permits that rely upon the change management strategy.

Nonetheless, the Agency encourages States to use the flexibility described in this preamble wherever they believe that the change management strategy will assure compliance with subpart GGG, while implementing the MACT standard in an efficient, streamlined fashion. The EPA intends to use this strategy where requested by a pharmaceutical facility and where the Agency would to be the permitting authority of jurisdiction under 40 CFR part 71.

It should also be noted that the described change management strategy is only tailored toward meeting the requirements of subpart GGG. Additional strategies are likely to be needed to address the consequences of a particular change relative to other relevant applicable requirements [e.g., minor or major new source review (NSR)], particularly when the change would cause an increase in the type or amount of air pollutants released.

Under EPA's interpretation, the Agency envisions that all title V permits implementing the pharmaceutical MACT will contain two principal structures: the incorporated pharmaceutical MACT standard and a detailed description of the array of process equipment, control devices, and initial operating conditions at the subject facility. In addition, the title V permit may contain a third structure implementing the change management strategy through prior approval of reasonably anticipated alternative operating scenarios [see section 70.6(a)(9)].

First, as it must under title V and part 70, the title V permit will contain permit terms and conditions that incorporate subpart GGG. These permit terms will include the requirements of the MACT rule applicable to PMPUs and other equipment that comprise pharmaceutical manufacturing operations, including all requirements for identifying affected emissions sources and applicable emission standards, calculating emissions, demonstrating compliance (e.g. requirements for the operation of control devices), and for testing, monitoring, record keeping and reporting.

The second permit structure, from the NOCSR submitted by the source owner, shows current operations and how the source is complying at that time with all the relevant requirements of subpart GGG (which were incorporated as the first permit feature). Named and described in the permit

are the specific processes in operation at the time of the NOCSR and all those that will be run during the term of the permit; the PMPUs and other regulated emissions equipment and activities associated with the pharmaceutical manufacturing operations; the linkages between identified emissions points and control devices used for compliance with the standard; and the linkages between the identified emissions points and their associated compliance obligations under subpart GGG. The calculations demonstrating compliance must be submitted by the source in support of these linkages.

The third permit structure addresses the management of frequent changes at pharmaceutical facilities subject to subpart GGG. This structure generally will allow permit revisions at pharmaceutical facilities to be avoided without sacrificing compliance assurance, in instances where reasonably anticipated alternative operating scenarios can be established in title V permits and supported with detailed operating logs (onsite records). If a source owner or operator can reasonably anticipate the type of changes and operating scenarios relative to the current operations defined by the NOCSR (i.e. the baseline operating scenario) that will use the equipment identified in the permit and will occur over the life of a title V permit, part 70 provides for the permitting of such changes through

alternative operating scenarios. However, because equipment configurations at pharmaceutical facilities can change frequently (and without complete predictability) in response to product changeovers, new drug introductions, and process improvements, the allowed operating scenarios need to be constructed in the title V permit in a “menu” format.

Under the permit menu for subpart GGG, a pharmaceutical source will be able to vary its array of processes and control devices from the permitted baseline scenario without need for permit revision, provided that these ways have been preapproved as alternative operating scenarios. This could include shifting process equipment, adding replacement process equipment, eliminating equipment within the same process, or changing the type or amount of solvent in order to improve existing processes or to add new processes. These changes, however, must not exceed the capacity of the control and process equipment as set out in the permit, and must always comply with the permit and all applicable requirements. The Agency again notes that such changes occurring under the change management strategy are preapproved for subpart GGG purposes only and other actions and/or strategies are necessary where other applicable requirements are implicated by such changes.

The change management strategy also addresses the addition of new condensers and of new process equipment

subject to subpart GGG. Condensers are the only new control devices currently that may be advance approved and only in limited circumstances (see section VI.L.2.b. Additional Considerations). Bringing new process equipment into service may be accomplished in two situations as a reasonably anticipated alternative operating scenario for purposes of subpart GGG, provided that the new equipment is preapproved in the permit and otherwise meets the requirements below.

The first situation involves the like-kind replacement of permitted process equipment which is functionally equivalent to and provides no greater production capacity than the equipment being retired. The replacement transaction, and identification of the new process equipment, must be recorded in the OSIL along with other information necessary to reflect the changed operating scenario. Because the new process equipment is replacing the retired equipment that was specifically identified in the permit, the new process equipment need not be specifically identified in the initial permit in order to be preapproved. The preapproval approach does not allow the substitution of new process equipment for permitted equipment that will remain in service elsewhere at the source.

The second situation involves the addition of process equipment which already exists on-site but is not in current service. In order to be approved for purposes of subpart GGG, this equipment must be specifically identified in the permit in terms of its type and capacity. The Agency notes that the authority to preapprove such process equipment in the permit is limited to equipment for which the owner or operator holds a reasonable expectation that the equipment will be called into service over the 5-year life of the title V permit. Because this category of equipment already exists at the facility, and will be specifically identified in the permit with its capacity and type listed for review by the permitting authority, EPA, and public, the Agency believes such equipment may not only replace permitted, retired equipment, but may also augment permitted equipment in service and thereby increase production capacity at the source.

In both of these situations, the additions of such equipment must meet all provisions of the permit governing their operation, including the requirement to stay within the approved capacity of the control device to which their emissions are routed. Other situations involving process equipment may not be preapproved and are subject to the notice procedures of section 70.4(b) or the permit revision procedures of section 70.7. Options under the current

regulations are, however, expected to change (see section VI.L.3. Legal Considerations for discussion of anticipated treatment of subpart GGG requirements attaching to new emissions units under the upcoming part 70 revisions).

At the time a source wishes to undertake a change that could trigger different obligations under subpart GGG or its permit, the source will evaluate first whether the change is within the scope of an approved alternative operating scenario in the permit. If so, the source will select the appropriate compliance options from the alternatives approved in the permit and implement the change consistent with the terms of the permit governing such selection. The source would not be required by the permit to route emissions from specific process equipment only to the specific control devices that were linked to them in the initial detailed compliance baseline. Instead, the menu of alternative operating scenarios, described below, in conjunction with features of subpart GGG will allow a source to shift to the compliance obligations governing the change and, where applicable, to select among the control devices at the facility that the permitting authority has approved as capable of achieving compliance.

The menu of alternative operating scenarios is a combination of the first permit structure discussed above

(i.e., the requirements of subpart GGG) and some additional features. In particular, the menu consists of: (1) a description of the emissions sources (e.g., process vents, wastewater points of determination, storage tanks, and other regulated equipment components) subject to the pharmaceutical MACT; (2) the specific emission standard or standards that potentially apply to each source; (3) all control devices that have been approved by the permitting authority through performance tests or engineering analyses (as provided by subpart GGG) to comply with those standards; (4) the parameters to be monitored and data to be recorded specified for each control device, each process or equipment, as appropriate, as well as the monitored parameter values that indicate compliance (i.e., parameter trigger levels); and (5) the testing, record keeping and reporting provisions that are relevant to each type of process or emissions source.

Whether a change can be accommodated within a preapproved alternative operating scenario from the menu depends on certain boundary conditions governing such use. These boundaries primarily depend upon: (1) the performance capabilities and any capacity limitations on control devices as approved in the permit for compliance;[1] (2) whether

[1]Note that these limitations must include restrictions on the amount of HAPs and, where relevant, the type of HAPs which can be routed to the device. It may be necessary to

subpart GGG's provisions governing that change are limited to replicable operating procedures (ROPs) for determining emissions and applicable emissions limits; (3) whether changed emissions fall within the performance limits of (1) above; and (4) whether the approved monitoring approach remains applicable. The ROPs must be capable of yielding the identical compliance assessment whether applied by the source, permitting authority, EPA or member of the public. That is, the results from using these procedures are the same regardless of who uses it and when. The ROPs must be scientifically credible and be based solely on nondiscretionary steps and on objective data (where data are required). These ROPs are contained either in the standard itself or established during the title V permitting process. Where the applicable subpart GGG requirement is not already such a procedure, but one that can be established during the permit process (see later discussion as to which requirements are eligible), then the source would propose it and the permitting authority would specifically need to approve it, including any limits on its use, during a title V permit process that is subject to EPA and public review.

Where a permit would contain the change management structure, the source's on-site documentation, as required

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include other restrictions, e.g., total organic compounds that define the capacity and the performance of the control device.

by subpart GGG (section 63.1259(b)(9)), will include an up-to-date operating log for alternative operating scenarios, [also required by section 70.6(a)(9)(i)]. The on-site implementation log (OSIL) must record sufficient information to show the compliance obligations of each specific operating scenario in advance of its operation.

Accordingly, the OSIL must include for each process:

(1) a description of the process and the type of process equipment used: (2) an identification of related process vents and their associated emissions episodes and durations, wastewater PODs, and tanks; (3) the applicable control requirements of this subpart, including the level of required control; (4) the control or treatment devices used, as applicable, including a description of operating and/or testing conditions for any associated control device; (5) the process vents, wastewater PODs, and tanks (including those from other processes) that are simultaneously routed to the control or treatment device(s); (6) the applicable monitoring requirements of this subpart and any parametric level that assures compliance for all emissions routed to the control or treatment device; (7) calculations and engineering analyses required to demonstrate compliance; and (8) a verification that the operating conditions for any associated control or treatment device have not been

exceeded and that any required calculations and engineering analyses have been performed.

The OSIL, in conjunction with and the information contained in the permit, monitoring records, and any other available information and belief formed after reasonable inquiry, will provide the basis for making annual compliance certifications under section 70.5(d). Moreover, this information will allow an enforcement authority to verify when processes were being operated, to identify which emissions points from each process were controlled and how, and to determine whether the control devices were operated at performance levels that assured compliance with subpart GGG. The permit would require the source to submit a quarterly report of the new operating scenarios contained in to the OSIL to the permitting authority and to certify to its truth, accuracy and completeness pursuant to section 70.5(d). For reporting purposes, a change to any of the elements defining an operating scenario (see above) which have not previously been reported, except for element (5) above, shall constitute a new operating scenario. The permit shall also require that monitoring data, including that relevant to the identified parameter trigger levels, be submitted semiannually (except that deviations must be reported promptly). The source or the permitting authorities would then make compliance information and the

OSIL reports available to EPA or members of the public upon request, consistent with confidential business information protections.

In establishing alternative operating scenarios in a title V permit, the source would propose performance levels and operating limits for control devices to be used for compliance. Except for condensers (see section VI.L.2.b. Additional Considerations), sources would then demonstrate compliance using control devices operated to accommodate the range of anticipated emissions episodes [i.e., a worst-case scenario(s) as provided in section 63.1257(b)(8)(i)]. The source must provide to the permitting authority in the NOCSR control device testing information and results (or other prescribed documentation), and monitoring provisions with parameters to be monitored to show compliance with the rule. Establishing monitoring parameter levels correlated to the required emissions reduction (i.e., trigger levels for compliance) assures compliance for anticipated worst-case emissions. This provides a source with considerable flexibility since most, if not all, changes to the source are likely to fall within the permitted worst-case emissions boundary and would not trigger a permit revision.

In some situations, the source may wish to establish multiple trigger levels for the same monitored parameter within the normal operating range of an existing control

device, each of which would assure compliance for different specifically defined emissions profiles. Thus, within the constraints of a control device's capacity, the title V permit may establish more than one enforceable trigger level for an operating parameter to accommodate most common kinds of anticipated operations without the need for a permit revision. A ROP in the permit must be used to calculate the emissions profile of any proposed change and match the new emissions profile to the appropriate operating parameter trigger level that assures compliance with subpart GGG. For example, in a system with three separate trigger levels for the same parameter, which have been predetermined in the permit, assume that the projected emissions associated with a particular change would require the level of control corresponding to the second trigger level. As a result, the calculated emissions would exceed the emissions profile associated with the first cutoff (and its lower level of control), would correspond to the emissions profile covered by the second and meet its required parameter trigger level, and would not meet the emissions profile characteristics and not require the greater control associated with the third trigger level.

For sources employing the change management strategy, the permit shall provide that a violation of the ROPs, a violation of other conditions implementing the change

management strategy, or a violation of the monitored parameter trigger levels (as applicable and recorded in the OSIL) would be a violation of the permit and of the control device trigger operating limit, and a violation of the emissions limit where specifically provided for by the standard (e.g., an exceedance of the outlet gas temperature for a condenser). The EPA notes that neither the change management strategy nor the OSIL can alter any obligations that the source has to comply with either the permit or the MACT standard itself. While permitting authorities may extend the permit shield in section 70.6(f) to the permit terms and conditions of each alternative operating scenario contained in the permit, assuming the State program has a permit shield provision, this permit shield may not be applied to the specific compliance-related changes which are only recorded by the source in its OSIL (see section VI.L.3. Legal Considerations). Like CAA section 502(b)(10) changes, most administrative permit amendments, and MPMs which do not undergo prior public review [see sections 70.4(b)(12)(i)(B), 70.7(d)(4) and 70.7(e)(2)(vi)], the part 70 permit shield may not extend to an OSIL or source determinations made pursuant to the change management approach that have failed to undergo prior EPA and public review. The source's compliance with those parameter levels recorded in the OSIL

will not shield the source against challenges to the source's compliance with subpart GGG.

To illustrate the change management permitting strategy, suppose a pharmaceutical source undertakes a process improvement project that replaces two steps in an existing pharmaceutical process with one new step. This project results in the elimination of two existing process vents from the process and the addition of a new vent. No new equipment is involved. Further, suppose that subpart GGG requires the existing process and the proposed process change to meet the 93 percent reduction requirement for process vents, and the source opts to meet that limit by ducting all vents from the process to an existing thermal oxidizer. As a first step, the source owner/operator must determine whether and to what extent the previously established baseline emissions profile for the process will change. To do this, the owner/operator will calculate the uncontrolled emissions from the new vent using the equations provided in the MACT rule (and incorporated into the permit). The new process step involves the following emissions-related activities: vapor displacement (Equation 8 in section 63.1257(d)(2)(i)(A) of the rule), heating (Equations 10-17), and depressurization (Equations 18-29). In calculating emissions, the owner/operator must supply the physical characteristics from the process batch production

procedures as inputs to the required equations. This description is the material used and the procedures followed exactly by the source to perform the process each time the specific product is produced. The process batch description includes details such as: the amount and type of raw materials to be used in each batch, the mixing and heating cycle durations, the final temperature of the heated ingredients, reflux rates, and the temperature of the reflux condenser.

Once the emissions from the new process step are calculated, the owner/operator adds these emissions to the previously documented emissions from the process and subtracts the emissions from the two process steps that were eliminated to determine the total emissions to be routed to the thermal oxidizer. A revised emissions profile for the process is now established. Next, the owner/operator must evaluate whether the thermal oxidizer still assures compliance with the 93 percent reduction requirement. Under the source's title V permit, the owner/operator will have calculated and documented (and the permitting authority would have approved) the worst-case emissions profile that could be accommodated by the thermal oxidizer. The owner/operator compares the emissions profile in the worst-case analysis with the improved process emissions. If the worst-case emissions profile will not be exceeded, the

changed process will comply with the standard, and the existing title V permit does not have to be revised (unless required to assure compliance with applicable requirements other than those of subpart GGG). If a new worst-case scenario would be created by the change, a permit revision must be undertaken to determine whether the change can be made. In order to support the permit revision, the owner/operator will have to perform additional analysis or testing, as required by the MACT rule and/or the permitting authority, to show that the oxidizer has sufficient capacity to control the new scenario to meet subpart GGG. This may require a corresponding revision to the monitored parameter compliance trigger level in the permit as well.

As stated earlier, the owner/operator is required by the MACT rule to keep records of all calculations performed to support the process improvement change. Thus, the on-site records include results of calculations to determine emissions from the new process step and total emissions from the improved process, and the comparison of emissions from the improved process with the previously established worst-case emissions analysis. If the change can be made without permit revision, the owner/operator also is required to maintain records in the OSIL showing when the change was made and how the new vent is controlled. In addition, the permit must require that the source operate consistently

with the calculations made for the operating scenario described in the OSIL. Such consistency, however, does not protect a source from violations of the standard, where the calculations are in error or otherwise fail to assure compliance with subpart GGG.

In the example presented above, the new process involves emissions-related activities that are covered by the ROPs contained in subpart GGG. However, some activities may not fall under operations for which equations have been provided in the standard. In many such cases, the change management strategy allows the source to submit for approval its proposed methodology for quantifying these emissions. Under this approach, the permitting authority would have the opportunity to evaluate the proposed methodology and, if judged replicable, by the permitting authority - with EPA and public review, establish this methodology in the title V permit. The ROPs could be established in the permit only through the permit issuance, permit renewal, or significant permit modification process. Where they are approved and upon their incorporation into the permit, the source must then use these procedures, as applicable, to determine if subsequent changes qualify for advance approval without need for permit revision under the change management strategy. The EPA intends to issue additional guidance to inform the

development, review, and approval of such ROPs during the permitting process.

For example, the MACT rule does not give exact procedures or formulae for calculating wastewater characteristics needed to determine control requirements. Instead, the rule states that HAP concentrations in wastewater are to be determined based on testing, knowledge of the wastewater stream (using a mass balance approach or one relying on published water solubility data), or bench-scale or pilot-scale testing (see section 63.1257(e)(1)). To explain the development of ROPs to address this requirement, a more specific situation must be described. Suppose that the process improvement project above includes an extraction that was not previously part of the process, resulting in a new wastewater stream which the owner/ operator wishes to treat using an existing steam stripper. In order to create the necessary ROP for determining the wastewater characteristics of streams, the owner/operator must first establish a methodology to determine this for the baseline scenario. During the initial compliance demonstration/permitting process, the owner/operator in this example would do so by proposing to determine the concentration of a partially soluble HAP in the aqueous phase of an extraction when a single organic compound is present by assuming that the concentration will be at the

maximum possible value based on the solubility value found in standard reference texts. This procedure, along with the batch description and the number of batches to be produced each year, provides a ROP for determining the characteristics of the extraction step wastewater stream (i.e., HAP concentration and annual HAP load). After approval by the permitting authority, the ROP can be used for new or modified extraction wastewater streams to characterize the stream and to determine whether the stream is subject to treatment under the MACT standard per section 63.1256(a)(1)(i). [Note that this ROP would apply only when a single organic compound is present. A separate ROP would have to be developed and applied in other cases.]

In addition to this procedure, the owner/operator must also establish a replicable procedure to compare the wastewater characteristics associated with a change to the worst-case capabilities of the treatment unit. Accordingly, the appropriate operating parameter and the trigger level necessary to assure compliance with the standard must be established in the permit. The owner/operator may wish to establish more than one such trigger level to allow steam stripper operating parameters to be varied according to the ability of the treatment unit to treat different streams being routed to it. In this example, assume that an existing process at the facility uses methyl ethyl ketone

(MEK) and generates an affected wastewater stream with 125,000 ppm MEK (based on the published solubility of MEK in water). Published data show that the Henry's Law Constant for MEK is 4.36×10^{-5} atm/gmole/m^3. Assume further that the initial steam stripper compliance demonstration for MEK removal indicated that a liquid/vapor (L/V) ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum of 2,300 pounds per hour) are required to achieve compliance.

Next, assume that a second existing process at the facility uses N,N-Dimethylanaline (DMA) and generates an affected wastewater stream with 16,000 ppm (based on the published water solubility for DMA). Published data show that the Henry's Law Constant for DMA is 1.75×10^{-5} atm/gmole/m^3. Assume further that the initial steam stripper compliance demonstration for DMA removal indicated that an L/V ratio of 10.0 and an average steam feed of 3,100 pounds per hour (not to fall below an instantaneous minimum of 2,400 pounds per hour) are required to achieve compliance.

The Henry's Law Constant is a measure of the partition of a compound between air and water (i.e., the "strippability" of the compound). Thus, based on the compliance demonstration results above, the owner/operator could propose, and the permitting authority approve, the conditions below for inclusion in the title V operating

permit to assure compliance with subpart GGG for new and modified wastewater streams routed to the steam stripper. Note that these conditions would apply only to partially soluble HAPs with Henry's Law Constants equal to or greater than that of DMA. Other provisions would have to be made for soluble HAPs and for partially soluble HAPs with lower Henry's Law Constants, or the source would have to undertake a permit revision to address new streams containing HAPs of these types.

1. When the steam stripping unit is receiving wastewater containing one or more partially soluble HAP (and no soluble HAPs) and the lowest Henry's Law Constant for any of the HAPs is greater than or equal to 1.75×10^{-5} atm/gmole/m^3 but less than 4.36×10^{-5} atm/gmole/m^3, the stripper will maintain a maximum L/V ratio of 10.0 and an average steam feed of 3,100 pounds per hour (not to fall below an instantaneous minimum of 2,400 pounds per hour).

2. When the steam stripping unit is receiving wastewater containing one or more partially soluble HAP (and no soluble HAPs) and the lowest Henry's Law Constant for any of the HAPs is greater than or equal or 4.36×10^{-5} atm/gmole/m^3, the stripper will maintain a maximum L/V ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum 2,300 pounds per hour).

To illustrate the change management strategy for the wastewater requirements, assume in this example that a new extraction step will use methylene chloride which is listed as a partially soluble HAP in Table 2 of subpart GGG. Using the operating procedure already approved in the title V permit, the owner/operator determines that the new extraction step will generate a wastewater stream with 20,000 ppm methylene chloride (based on the published solubility of methylene chloride in water) and an annual load of more than 1 Megagram per year (based on the process "recipe" and maximum possible production rate or as limited by permit conditions). Thus, the new wastewater stream is subject to treatment under the MACT standard pursuant to section 63.1256(a)(1)(i)(A). Published data show that the Henry's Law Constant for methylene chloride is 2.68×10^{-3} atm/gmole/m^3. Since the Henry's Law Constant is greater than 4.36×10^{-5} atm/gmole/m^3, this stream can be discharged to the existing steam stripper provided the stripper is operated within the operating parameter trigger level established in the permit [i.e., maintaining a maximum L/V ratio of 12.7 and an average steam feed of 2,900 pounds per hour (not to fall below an instantaneous minimum of 2,300 pounds per hour)].

Based on this analysis, the new extraction step can be controlled by the steam stripper to assure compliance with

the MACT standard and the change can be instituted without a permit revision. The owner/operator shall maintain in the on-site log records of all the procedures used (including the characterization of the new wastewater stream, the determination that the stream is subject to treatment under subpart GGG, and the comparison with the stripper's two-level Henry’s Law Constant cutoffs) and the process and treatment unit parameters needed to verify ongoing compliance (including when the process change was instituted, when the modified process is in operation, how the wastewater stream is controlled, and the L/V ratio and average steam feed rate for the stripper). Moreover, the permit shall require the recordation in the log of additional applicability and compliance information, as necessary to assure compliance with subpart GGG.

b. Additional considerations. Additional options are available to permitting authorities designing flexible title V permits to accommodate, without permit revision, emissions changes controlled by a condenser. Instead of requiring that all changes affecting emissions must meet the MACT standard under constant operation of an existing condenser at worst-case conditions, a permitting authority may issue permits where the condenser may be operated at different temperatures correlated to actual emissions profiles. Permits (through their terms which incorporate

subpart GGG) will already contain the replicable means to calculate emissions profiles for process changes and the condenser exit temperatures required to control them. The Agency may explore development of similar approaches for other control devices, but recognizes that any such approaches before being incorporated into the permit would have to: (1) be calibrated in the field for a particular site; (2) meet rigorous tests to demonstrate scientific credibility, replicability, and practical usage; (3) ultimately assure compliance with subpart GGG and all other relevant applicable requirements; and (4) be evaluated by EPA to determine whether such an approach is possible for other control devices.

New control devices are, in general, not preapproved and their operational limits must be the subject of a permit revision which incorporates this information into the title V permit. The Agency, based on its ongoing efforts to assure compliance, has found that the proposed new control devices must be subject to a prior site-specific evaluation by a reviewing authority in order to assure that the control device is adequately sized and that reasonable assumptions were used related to its performance. This general limitation is not related to change management except where the addition of new productive capacity (e.g., a new process using new process equipment) would require control capacity

beyond that previously approved in the permit. Currently, the only exception to this limitation under the change management strategy involves the preapproval of certain new condensers. Here the permitting authority may advance approve new condensers but only to the extent that they are like-kind replacements for those currently approved in the permit or are specifically identified from an inventory of preapproved, existing (but not currently in-service) devices at the facility.

With respect to Leak Detection and Repair (LDAR) work practice standards under subpart GGG, changing to a new process or modifying an existing one would not affect the content of the title V permit. These LDAR requirements apply broadly across a site as a work practice standard to the fugitive emissions of many types of equipment components at a facility. This equipment typically includes pumps, pressure relief devices, valves, and connectors, which typically number in the thousands at pharmaceutical facilities. The individual components subject to the LDAR requirements do not need to be specifically listed in a facility's title V permit.[2]

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[2]The rule's LDAR provisions apply to significant numbers of emissions units, and typically do not involve different emissions control levels for equipment components subject to LDAR requirements. The LDAR requirements typically are written as a set of work practice standards that either apply to a piece of equipment or do not apply. To ensure that an affected source properly identifies those

Instead, the title V permit shall contain a general identification in the title V permit of the equipment covered and the associated compliance obligations that will suffice to assure compliance with the LDAR requirements. Accordingly, a separate up-to-date list of affected equipment components must be maintained as required by the extensive LDAR record keeping provisions. Given that no specific list of components is required in the permit, and the permit shall comprehensively cover the equipment component types subject to LDAR requirements, the content of the permit will be unaffected by changes to such components that occur in the course of introducing a new process or modifying an existing one.

Finally, the promulgated rule features alternative standards for any process vent and storage tank emissions sources that are ducted to control devices. These alternative standards require achieving a specific total organic carbon (TOC) concentration of 20 ppmv and a concentration of hydrogen halides and halogens of 20 ppmv

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pieces of equipment subject to the LDAR requirements under subpart GGG, the regulation is including a requirement to maintain a separate list of affected equipment components within the LDAR record keeping provisions. For these reasons, and because the LDAR requirements apply to so many equipment components at pharmaceutical facilities, the Agency believes it is appropriate not to require the individual components to be specifically listed in the title V permit for these facilities.

from the outlet of control devices. Sources using these alternative compliance options are likely to reduce significantly (particularly where a single control device services multiple processes using nondedicated equipment) the required record keeping and reporting and to simplify the change management strategy. For example, a source could specify processes (which do not emit hydrogen halides or halogens), each of which vents to a carbon adsorption bed documented to achieve 20 ppmv TOC. In this case, several of the permit elements implementing the previously described change management strategy could be eliminated (e.g., provisions related to the menu of compliance options and suitable control devices, and the monitoring of parameter values), and much of the record keeping could be reduced to tracking which processes are routed to the common control device and monitoring TOC outlet concentrations to show compliance with the 20 ppmv standard. However, other monitoring and record keeping requirements (e.g., flow rate maximum through the control equipment) may be needed in the permit to address periodic monitoring or compliance assurance monitoring and non-MACT applicable requirements (e.g., minor NSR) which limit the total atmospheric loading from the source.

3. Legal Considerations

The management of change strategies set forth in this preamble represent the Agency's effort to devise an innovative approach to deal with the frequent process changes that take place at pharmaceutical manufacturing facilities without the need for equally frequent revisions to their permits. The strategies rely upon a number of factors (see section VI.L.4. Supporting Rationale for Recommended Strategy) that, while perhaps not unique in this industry and in subpart GGG, are specific to it, and the Agency is uncertain whether and to what extent they may have application in other contexts. These factors underlie the Agency's present belief that the change management strategy in its practical application will assure compliance with subpart GGG through title V permits, and satisfy the objectives of part 70 and title V of the Act.

This approach is frankly an experimental one. Although EPA believes that the legal interpretations upon which the Agency is relying are consistent with the Clean Air Act and existing regulations, some aspects of this approach strike out in new and untried directions. In effect, EPA is conducting a pilot program to demonstrate whether permits that allow changes under subpart GGG can be made: (1) without permit revision or 7-day advance notification under section 502(b)(10); (2) based on the source's

application of clear, simple definitions and ROPs; and (3) while contemporaneously being recorded in detailed operating logs. The EPA will therefore be testing its belief that such an approach will be practicably enforceable, will assure compliance with the standard—obtaining the emissions reductions required by the standard, and will satisfy the objectives of title V of the Act.

The 40 CFR parts 70 and 71 provide for the establishment in title V operating permits of terms and conditions for reasonably anticipated operating scenarios at a source.[3] A source may then preapprove alternative operating scenarios in its permit and switch among these scenarios in response to operational demands, without obtaining a permit revision to account for the previously approved new operating scenarios and their different applicable requirements. All title V permits, including those implementing alternative scenarios, must contain terms and conditions sufficient to assure that each operating scenario will comply with all applicable requirements and

[3]Because part 71 addresses alternative operating scenarios in the same fashion as part 70, the Agency believes that part 71 is equally amenable to the management of change approach described in this section. For ease of discussion, this section will refer to the relevant provisions of part 70 in discussing the management of change approach. The EPA intends, however, that the part 70 discussions in this section should have equal force and application to the corresponding provisions of part 71.

will meet the requirements of part 70. Pursuant to section 70.6(a)(9), the source must identify such scenarios in its permit application and the permitting authority must approve the scenarios for inclusion in the permit. The permit terms and conditions necessary to implement the alternative operating scenarios must also require the source to record contemporaneously in an on-site log the scenario under which it is operating, upon changing from one scenario to another. The contemporaneous record of the present operating scenario that the source maintains on-site serves to document for important inspection and enforcement purposes that the source is in compliance with the source's permit terms and conditions.

The determination of when alternative scenarios are "reasonably anticipated" and would meet the requirements of section 70.6(a)(9) is not amenable to a rigid legal formula that can dictate through general guidance what types of permit terms and conditions will ensure that a source's future operations comply with these requirements. Instead, there must be legal and practical considerations that inform this determination within EPA's reasonably broad discretion to do so. The Agency has identified certain preliminary legal boundary considerations and conditions for implementing reasonably anticipated operating scenarios to meet subpart GGG, pending further experience with pilot

projects and permits and further guidance or rulemaking on the subject.

The structure and nature of title V permitting will determine how permit terms and conditions may be developed to reasonably anticipate alternative operating scenarios. The part 70 regulations govern the content requirements for permit applications and permits in section 70.5 and 70.6, respectively, and these sections will govern how reasonably anticipated alternative operating scenarios must be addressed in permit applications and permits as well. For example, all part 70 permit applications must contain information “for each emissions unit at a part 70 source,” which includes a description of the source’s processes and products for each alternate scenario identified by the source [sections 70.5(c) and (c)(2)]. Section 70.6(a)(9) in turn makes clear that a source must identify in its application each reasonably anticipated operating scenario for which it intends to include permit terms and conditions.

Along the same lines, section 70.6 requires that all part 70 permits include emissions limitations and standards, monitoring, record keeping, reporting, compliance and other requirements to assure compliance with all applicable requirements. Section 70.6(a)(9) again makes clear that the permit terms and conditions governing alternative scenarios must meet these requirements. Applicable requirements

generally fix a source’s compliance obligations on an emissions unit or activity, control equipment, process, or combination thereof. Permitting alternative scenarios requires the ability to reasonably anticipate future emissions units, future operational details, and the compliance obligations under each applicable requirement associated with each operational state, as necessary to assure compliance with each applicable requirement.

The permit terms and conditions governing each alternative operating scenario must assure compliance with all part 70 and applicable requirements at all times. This means that the permit terms and conditions must assure compliance with all relevant requirements at the time of initial permit issuance and at the time that changes to alternative operating scenarios are undertaken in the future. Upon a source’s change from one operating scenario to another, the terms and conditions of the permit must continue to fully and accurately reflect the source’s compliance obligations under all requirements applicable to the change. If a source changes to an operating scenario that was not provided for in its permit, or if a change undertaken by a source triggers compliance obligations that are not fully and accurately reflected in the permit, then the source would be subject to the permit revision, permit reopening, or section 70.4(b) notification provisions, as

applicable, under the part 70 regulations prior to making the change.

The permitting of established operating scenarios at a part 70 source that are fully known, identified and expected is straightforward. Such situations are accounted for in part 70 permits through terms and conditions that specify the emissions units and activities, provide required citations to applicable requirements, and supply the additional range of permit provisions required in a complete title V permit. Reflecting current equipment and activities, existing operating configurations, and presently applicable regulatory requirements, these operating scenarios present no difficulty to incorporating into an operating permit sufficient terms to meet the permit content requirements of part 70.

The preapproval and permitting of reasonably anticipated alternative operating scenarios is somewhat different in that their associated emissions units and activities, operational configurations, and applicable requirements may not be known with the same specificity as previously established operating scenarios. Nonetheless, in order to be included in the permit as alternative operating scenarios, the source must provide sufficient specificity for those scenarios to allow the permitting authority to determine the applicable requirement(s) and establish permit

terms and conditions assuring compliance with those applicable requirements and the requirements of part 70. The EPA believes that it is a reasonable interpretation of section 70.6(a)(9) to require only that permit terms and conditions reasonably anticipate the emissions units and activities, operational configurations, compliance obligations, and other relevant information associated with each alternative operating scenario, so long as the permit terms and conditions assure compliance with relevant applicable requirements at all times. Conversely, there may be new or different requirements that attach to an operating scenario at the time that the source changes to that scenario, or other material differences from the permitted operating scenario may have arisen, such that the change and its regulatory requirements are not covered by the permit. If the permit does not reflect those requirements because they were not previously established, then the source, as provided for under the part 70 regulation, must account for all requirements applicable to that operating scenario, whether through a permit revision or advance notification or in response to a permit reopening.

The permit terms needed to approve alternative operating scenarios to assure compliance with all applicable requirements and to be reasonably anticipated may, in general, be expected to vary by source category, the

different types of emissions units and operating scenarios present at sources, and the inherent uncertainty of predicting future operating conditions and market demands. In particular, the authorizing permit limits might vary based on several factors which primarily include, but are not necessarily limited to: the types and specific terms of the applicable requirement(s); the complexity of the facility; whether the type or quantity of emissions will change widely; whether different pollution control devices will be needed; the ability of the permitting authority to develop practicably enforceable permit terms for alternative scenarios and to define the limitations of the control and monitoring approaches; the potential for future technology advances (where such advances are linked to the nature of the applicable requirements); and the presence of discretion in determining the applicability and/or the compliance status of the change. These factors are not always present, are often interdependent, and can range widely in their ability to affect whether compliance with the applicable requirements can be assured and whether operating scenarios can be reasonably anticipated.

Because permit terms and conditions for reasonably anticipated operating scenarios implementing subpart GGG will be based in part upon ROPs that are designed to yield site-specific compliance details at the time of a change,

EPA believes these procedures must be capable of yielding the identical compliance details, such as compliance triggers for monitored control device parameters, whether applied by the source, permitting authority, EPA or member of the public. Thus, the permit terms and conditions which incorporate such procedures will produce predictable and certain compliance results at the time of a change.

The EPA is testing this approach to determine in practice the appropriateness of allowing pharmaceutical facilities to determine the specific compliance obligation(s) under subpart GGG that apply to a particular process change through reliance on the standard's ROPs and ROPs that gained earlier approval through the permitting process. The form of the ROPs in subpart GGG and the nature of pharmaceutical manufacturing operations, in conjunction with the other safeguards and features of the change management strategy, are central to the Agency's willingness to conduct this pilot strategy here.

A source's compliance with permit terms and conditions for reasonably anticipated operating scenarios based upon properly implementing ROPs derived from subpart GGG will be "deemed" compliance with the applicable requirement for section 70.6(f)'s permit shield only to the extent that the source applies the procedures correctly. While permitting authorities may extend the permit shield to the permit terms

and conditions of each alternate operating scenario implementing subpart GGG, assuming the State program has a permit shield provision and assuming it is applied in the permit consistent with section 70.6(f), part 70's permit shield may not extend to on-site implementation logs required by section 70.6(a)(9)(i). Like section 502(b)(10) changes, most administrative permit amendments, and MPMs that do not undergo prior public review [see sections 70.4(b)(12)(i)(B), 70.7(d)(4) and 70.7(e)(2)(vi)], the part 70 permit shield may not extend to an implementation log that has failed to undergo prior public review. Nor may the shield extend to the outcomes of ROP equations, applicability or nonapplicability determinations, or other compliance determinations recorded only in the OSIL. While a source will be required to use the implementation log to follow compliance triggers that implement the permit and one or more applicable requirements, the permit shield is not available to deem the source’s compliance with those compliance triggers to be compliance with the permit or the applicable requirement.

In addition to permitting authority review, part 70 permits are subject to public and EPA review to ensure that the permit terms and conditions assure compliance with all applicable requirements and the requirements of part 70. An essential consideration in determining whether permit terms

and conditions reasonably anticipate operating scenarios is whether the permit provides sufficient information and opportunity for the public and EPA to determine and comment in a meaningful fashion whether the terms and conditions of reasonably anticipated operating scenarios meet, and will continue to meet, all applicable requirements (including those of subpart GGG) and part 70 requirements.

Permit terms and conditions reflecting alternative operating scenarios, like all part 70 permit terms and conditions, are subject to the possibility of EPA objection and public petition under section 505(b) of the Act. In addition, operating permits are subject to the possibility of reopening by permitting authorities or EPA under sections 502(b)(5) and 505(e) of the Act. Permit terms and conditions of alternative operating scenarios that fail to reasonably anticipate future operating scenarios, emissions units and activities, and their associated compliance obligations may be subject to EPA objection, public petition, or reopening for cause. Failure by permitting authorities to submit information necessary for the public and EPA to review proposed permits adequately constitutes grounds for an EPA objection under section 70.8(c)(3)(ii), but information necessary for the review of alternative operating scenarios should be guided by the principle that permit terms and conditions must reasonably, but not

perfectly, anticipate alternative operating scenarios. (Note, however, that the permit and any alternative operating scenarios must fully and accurately govern changes that a source believes to be pre-approved at the time of the change, or else the part 70 permit revision, permit reopening, or 502(b)(10) notification provisions, as applicable, must be followed prior to making the change.)

Section 70.6(a)(9) affords permitting authorities the latitude to impose permit terms and conditions to assure that alternative operating scenarios meet all applicable requirements and the requirements of part 70. Such terms and conditions may go beyond compliance obligations strictly incorporated from applicable requirements being implemented pursuant to the alternative scenario. For example, in order to assure compliance with an applicable requirement or part 70, a permitting authority may determine that it is necessary to impose additional safeguards for alternative scenarios, such as requiring new emissions units or emissions units operating under different scenarios to be routed to a common, existing control device with preapproved capacities and operating parameter limitations. A permit might also require additional monitoring, record keeping, or reporting, or require that the source undertake a permit revision should future changes deviate materially from the reasonably anticipated scenarios in a manner that

jeopardizes the permit's ability to meet all part 70 and applicable requirements. Finally, the permitting authority may require additional details and compliance information in the source's on-site log to ensure that the record of the source's current operating scenario, in conjunction with the permit terms and conditions, assures compliance with all requirements in a manner that serves important compliance, inspection, and enforcement purposes. If the permitting authority determines that these additional safeguards are necessary for an alternative operating scenario to assure compliance with one or more applicable requirements, the permitting authority need not approve the alternative scenario in the permit without such measures.

The preceding legal considerations apply in general to alternative operating scenarios implementing subpart GGG. It is also important to distinguish further among categories of alternative operating scenarios, on the basis of whether new versus existing process equipment or control devices are involved, and on the basis of the specificity of the equipment identification, operational configurations, and linkages to applicable requirements in the permit. Of the three categories of alternative operating scenarios described below, the Agency is prepared to test the appropriateness of the second and third approaches under section 70.6(a)(9) for purposes of implementing subpart GGG.

First, there are alternative operating scenarios for existing emissions units and activities at a part 70 source, covering specifically identified operational states or configurations for specified emissions units. In its simplest form, this category is exemplified by an emissions unit such as a fossil fuel-fired boiler that has two fuel burning options, which are each subject to a different applicable requirement with different monitoring obligations. The task of reasonably anticipating the terms and conditions of an alternative operating scenario such as this is furthered by the relative ease of specifying the emissions unit and its activities, operational configurations and conditions, and associated applicable requirements. A source's past operating experience as well as future operational certainty, founded upon existing emissions units and activities, will make permitting of such alternative scenarios more like the task of permitting a source's current operating scenario.

The second category of alternative operating scenario, being tested to implement subpart GGG, covers the combination and reconfiguration of existing emissions units and control devices in alternative operational states and configurations that are not specifically identified in the permit. As described in greater detail in section VI.L.2.a General Strategy for Change Management, a permit menu of

alternative operating scenarios may be constructed to govern only the subpart GGG compliance obligations of process equipment and control devices specifically identified in the permit. If a change to an alternative operating scenario preapproved in a permit menu involves only the reconfiguration of existing, permitted emissions units or control devices, and the change remains within the capacity of an approved control device to which it is routed; if subpart GGG's provisions governing that change are limited to ROPs; and if the other criteria of the change management strategy are satisfied (including the contemporaneous recordation of compliance information in the OSIL), then EPA is willing to test whether such an approach will assure compliance with subpart GGG through title V permitting. While this approach will not specify future applicability determinations and establish the specific compliance obligations of particular process configurations to the same degree as the first category of alternative operating scenarios, EPA anticipates that the approach will nonetheless assure compliance with subpart GGG and otherwise meet the requirements of part 70.

The third category of alternative operating scenario, again tested in this pilot permitting approach to subpart GGG, covers new emissions units and condensers that are not in service at the time the operating scenario is

established in the permit, but that may be preapproved (with respect to subpart GGG requirements) in two circumstances only. First, the permit may preapprove future like-kind emissions units or condensers that will replace retired emissions units or condensers without increasing permitted capacity. Second, the permit may preapprove specifically identified, on-site surplus processing equipment that may replace retired equipment or augment in-service equipment by increasing production capacity. The Agency believes that it is a viable interpretation of the existing section 70.6(a)(9) to allow alternative operating scenarios implementing today's standard to include permit terms and conditions approving in advance these categories and usages of new emissions units and condensers that will be subject to subpart GGG, if they meet the criteria discussed earlier in section L.2.a.

The EPA, in August 1994, proposed to allow use of the concept of alternative operating scenarios under section 70.6(a)(9) to provide advance approval to construct and operate new or modified units subject to NSR and section 112(g) (referred to as "advance NSR"). (59 FR 44460, 44472, Aug. 29, 1994). Under this proposal, advance NSR would have allowed permitting authorities to establish the applicable NSR or section 112(g) requirements before a reasonably anticipated project or class of projects

was constructed or modified, and then include that project's requirements in the part 70 permit for the facility. As a result, the project would be "preapproved" by the permitting authority, without the need for a later part 70 permit revision since the part 70 permit would already contain the relevant construction and operation requirements for the project.

In August 1995, EPA further clarified its advance NSR proposal by proposing to add a definition of advance NSR to section 70.2, and by explaining that, in EPA's view, a change subject to an advance approval scenario would not be a change under section 502(b)(10) of the Act (60 FR 45530, 45544-45, Aug. 31, 1995). Rather, it would constitute a switch to an alternative operating scenario under section 70.6(a)(9). As the 1995 preamble noted, this interpretation would have two advantages. First, it would allow the use of advance NSR for title I modifications, and avoid the limitation that changes made under section 502(b)(10) cannot be title I modifications. Second, and more important, the 7-day advance notification under section 502(b)(10) which attaches to each change made under that section would not apply to changes under the advance NSR approval. Consequently, where the State operating permit program allows for advance approval, and the permitting authority approves an alternative scenario

containing advance approval, the part 70 permit could allow a source to make the approved change without an advance notice or a part 70 permit revision.

Although the Agency has not finalized revisions to the part 70 regulations to adopt the proposed amendments to sections 70.2 and 70.6(a)(9) discussed above, the Agency is prepared to interpret the existing part 70 regulations for purposes of the change management strategy for subpart GGG approach to enable alternative operating scenarios to encompass advance approvals in the limited manner described in this notice. In other words, for purposes of the approach described in this section, EPA believes that it is a reasonable interpretation of existing section 70.6(a)(9) to cover the advance approval of the categories of new process equipment and condensers described in this notice, within the scope of alternative operating scenarios that may be included in part 70 permits. The concept of “reasonably anticipated operating scenarios” is expansive enough to encompass not only existing equipment that may operate under a different operating scenario reasonably anticipated to occur, but also to encompass new equipment that replaces permitted equipment (without increasing permitted capacity), and new surplus equipment that is on-site and specifically identified and pre-approved in the permit.

The Agency is prepared to advance these interpretations under the current regulations prior to any final action on the part 70 revisions that might adopt the proposed amendments, for purposes of implementing subpart GGG through the pilot approach for the change management strategy described herein. This interpretation may not be relied upon for purposes of implementing applicable requirements other than subpart GGG through title V permits. The EPA may extend this interpretation to other applicable requirements, however, in the context of an individual permitting pilot project in order to facilitate the development and evaluation of the change management strategy, along with other flexible permitting opportunities, for the pharmaceutical industry. The policies set forth in this section are intended solely as guidance for purposes of implementing subpart GGG, do not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party.

Other changes that a pharmaceutical facility undertakes that implicate subpart GGG requirements and that are not preapproved in the permit through the change management strategy or ordinary alternative operating scenarios, must be accounted for through part 70's permit revision or section 70.4(b)(12) or (b)(14) notice procedures, as appropriate. Such changes would include, but are not

necessarily limited to: changes among permitted, in-service equipment involving subpart GGG's provisions governing the change that are not limited to ROPs; changes that would exceed the performance capabilities or capacity limitations of approved control devices; changes involving the addition of new emissions units or control devices (including any control device other than condensers) that have not been approved pursuant to the categories discussed in section L.2.a; and other changes that are not otherwise preapproved in the permit. Finally, of course, changes that implicate applicable requirements other than or in addition to subpart GGG must be addressed in the manner required by the part 70 regulations.

In the proposed revisions to part 70 in August 1995, 60 FR 45530, EPA proposed an expeditious permit revision process for the incorporation of requirements that would not need source-specific tailoring. The process was referred to as "notice-and-go," since the source could operate the change as soon as it submitted a notice to the permitting authority, and would not need to wait for review or approval of the change by the permitting authority. The EPA further elaborated on the concept in a Federal Register notice announcing the availability of its May 14, 1997 draft final revisions to part 70, published on June 3, 1997, 62 FR 30289, where the process was called "notice-only."

As currently envisioned, the process would be available for changes that are: (1) subject to requirements taken directly from the applicable requirement; (2) where there is no creation of any source-specific requirements; and (3) the permitting authority allows the change to take place without the need for its review or approval. For example, incorporation into the permit of a compliance option specified in a MACT standard would be eligible for notice-only procedures, but the establishment of source-specific parameter ranges for monitoring the performance of a control device would not be eligible. The installation of a degreasing unit subject to the halogenated solvent cleaning MACT standard under subpart T of Part 63 would also be eligible, if the facility elects to meet the standard through one or more of the compliance options specified in the MACT standard. This change would be eligible for the notice-only process because the permit terms that apply to the change would be taken straight from the underlying requirement, and there would be no need to add monitoring requirements.

In the May 1997 draft, EPA would have required the source to certify compliance in the notice with all applicable requirements that apply to the change (in the case of subpart GGG, for example, a new unit being added). This certification requirement helps offset the lack of

review by the permit authority prior to operation of the change, since a source making a false certification would be subject to penalties, or to criminal fines in the case of a knowing violation. There would also be no permit shield available for “notice-only” changes, so if a source failed to identify one or more requirements that apply to a new unit, the requirements are nonetheless applicable, and the source would be liable for any violations of applicable requirements to which the change is subject.

The Agency anticipates that the notice-only category of the third tier of the part 70 revisions, if adopted as presently conceived, would accommodate the application of subpart GGG requirements to new process equipment and control devices through part 70 permit revisions. Part 70 permits implementing subpart GGG through the management of change approach described in today’s notice likely will have established source-specific requirements for existing control devices in the initial permit. The purpose of the notice-only procedures would be to revise the permit so as to identify new process equipment or control devices being added at the source, and to match up relevant permit requirements that apply to the new units. As noted at the outset of this section, however, it still may be necessary to address the consequences of a particular change relative to other relevant applicable requirements that may attach to

that change. Thus, changes must be evaluated under the part 70 permit revisions to determine what level of permit revision might be required to address other regulatory consequences of the change.

4. Supporting Rationale For Recommended Strategy

a. Overview. The EPA has initiated this pilot permitting strategy for subpart GGG based upon a preliminary view that the recommended approach will satisfy section 70.6(a)(9)'s expectations for "reasonably anticipated" alternative operating scenarios, and comport with title V's mandate that operating permits assure compliance with applicable requirements. In general, the Agency believes the change management strategy meets these criteria by relying upon the basic design and provisions of subpart GGG; the additional requirements under the policy for permits to contain terms that assure the proper identification and compliance of all alternative operating scenarios covered by the strategy; and the title V permit issuance, significant permit modification, or renewal processes, along with quarterly reporting to permitting authorities, to afford meaningful opportunities for the permitting authority, EPA, and the public to review the strategy proposed by a source, and oversee its implementation, for a particular location.

Notwithstanding these provisions and protections, the Agency is recommending that permitting authorities use the change management strategy only on a trial basis, and only with respect to subpart GGG. The EPA notes that the need to match that changes in emissions correctly to their applicable subpart GGG requirements is central to the purpose of section 70.6(a)(9). As a critical first step, certain key definitions (e.g., process vent, process) and other rule provisions must be interpreted by EPA or the permitting authority in the permit process before applying the relevant ROPs. The ROPs then objectively size and sort emissions changes relative to their subpart GGG obligations and assure compliance in part by routing the new emissions, as appropriate, to a control device with sufficient capacity. Use of these definitions and regulatory provisions could be open to interpretive disputes and misapplication of the standard. However, due to several factors (including the homogeneity of process equipment in the industry, the high accuracy with which emissions resulting from changes can be characterized, the existence of ROPs for determining emissions and the effects of emissions controls, and the validation of a source’s use of the relevant definitions, regulatory provisions, and ROPs during the title V permit process), EPA believes that there is a sufficiently low probability that sources will make

errors in applying these definitions and provisions during the implementation of the change management strategy. Accordingly, the Agency will determine on the basis of empirical results whether this strategy needs additional protections, whether it is an appropriate approach to permitting, and/or whether and on what basis it can be made available to a broader range of sources and standards.

b. Detailed Rationale. Subpart GGG is a process-based standard which has been carefully designed to provide the framework needed by the change management strategy to establish the preapproved family of alternative operating scenarios for reconfiguration of existing process equipment and to define the compliance obligations of operating scenarios involving the addition of certain new process equipment. This framework is defined primarily from three types of features found in subpart GGG. In total, these three features establish a means for demonstrating continuous compliance that must be repeatedly applied for process and operational changes at the source.

The first feature is comprised of requirements relating to the use of equations to estimate emissions from various pharmaceutical operations. These equations provide the ability to characterize a process or operational change’s effect on emissions in a replicable and accurate fashion. The equations incorporate proven chemical and

physical principles such as the Ideal Gas Law and Raoult's Law, and have previously been approved by the Agency (most recently in MACT standards for the Polymers and Resins Industry, subparts U and JJJ of 40 CFR part 63). Upon their incorporation into the permit and approval by the permitting authority, a source must use these equations to determine applicability of the standard and to demonstrate initial compliance with it. Subsequently, the source must use the equations to determine the emissions from changes in operations together with those from ongoing operations. Anyone using the level of emissions predicted from these equations would then determine in exactly the same objective fashion how to maintain compliance with subpart GGG while manufacturing different intermediate or final products.

The second feature providing flexibility is the requirement that control devices be designed to accommodate reasonable worst-case operating scenarios without need for revised operating parameters or operating conditions. This means that most changes that affect emissions can be handled by the devices. In all cases, compliance assurance is achieved by virtue of the requirement to compare the emissions profile associated with the change with the worst-case operation approved for the relevant control device(s) and to require a permit revision where the changed operation would present a need for greater control.

The third feature of the rule that facilitates operating changes is the record keeping requirements. In the OSIL, as described earlier (see section VI.L.2.a. General Strategy for Change Management) sources must keep a precise log of the operation of batches, the occurrence of any process or operational changes and associated changes in emissions, the requirements of subpart GGG contemporaneously applicable to each process under its new operational state, and the controls used to comply with these requirements. The information required by the permit, together with on-site records and the required calculations for the sizing of emissions sources and the sorting of changes relative to their subpart GGG requirements allows an inspector to determine initially and for any subsequent time period which activities from a listed process require control and the level of control that is required for each.

The rule enables the company's basic framework for the change management strategy to be incorporated into the title V permit. In addition, other permit terms are needed to assure that an appropriately useful scope of alternative scenarios can be reasonably anticipated and preapproved to meet section 70.6(a)(9) and that the compliance obligations of certain new process equipment (i.e., like-kind replacements and on-site surplus equipment identified in the permit) can be defined. The first of these terms applies to

operations that are not covered by ROPs as taken directly from the requirements in subpart GGG. Previous discussions of ROPs have alluded to two types, those that are included in detail in subpart GGG and those that are established in the title V permitting process to meet subpart GGG. The latter category is necessary because of the compliance flexibility that subpart GGG contains.

For the methodology that the source proposes to receive the status of a permit-required ROP for purposes of the change management strategy, the permitting authority must determine that the methodology is scientifically credible and is objectively replicable. The bottom line is that the ROP must be a procedure based solely on nondiscretionary steps and on objective data (where data are required) to accomplish these steps. Accordingly, the results from using these procedures are the same regardless of who uses them and when. Where the permitting authority preapproves ROPs, the permit shall require the source to use them over the defined range of similar operations (unless, of course, the source wishes to obtain approval of a different method under the permit revision process). The EPA would like to stress that the ROPs are only an important part of the compliance process established by following the standard and are not an alternative standard, monitoring, or test method.

Section 504 (a) of the Act provides the legal basis for establishing ROPs during the permit process. This section requires that title V permits contain emissions limits/ standards and other terms as needed to assure compliance with applicable requirements. In its White Paper Number Two issued in March 1996, EPA stated that title V permits pursuant to section 504(a) may contain terms which are not necessarily the terms of a particular applicable require-ment, provided that such terms assure compliance with this requirement. (see section II.A.2.d. and II.A.5.) The Agency believes that this same authority also supports development of a methodology as a ROP during the title V permit process, provided that its development is consistent with the provisions of the applicable requirement, following the methodology would provide the same degree of compliance assurance as would following the applicable requirement directly, and sufficient procedural safeguards are followed in its establishment.

Subpart GGG is consistent with establishing such methodologies. For example, it empowers the permitting authority to review and approve, as appropriate, a source’s proposed emissions estimating procedures for operations not covered by the standard’s equations. In addition, as part of the initial compliance determination process laid out in subpart GGG, the source is required to provide the specifics

of its calculations and engineering analysis procedures to the permitting authority as a matter of course. Subject to certain boundary conditions on its applicability and use, the specific source proposal can often be extended into a methodology to address future qualifying changes.

The EPA is testing whether reliance on this approach also provides equivalent compliance assurance to that provided from a case-by-case review implemented for the same change by the permitting authority. In the absence of the change management strategy, the permitting authority would evaluate the procedures used by the source each time a change was to be made. Thus, the permitting authority would be called upon to make the same judgements in either case; only the timing and frequency of the review and approval process would change. In the context of the strategy, the permitting authority and the source simply agree ahead of time on the replicable procedures that are to be used for a range of changes.

Finally, by requiring that the approval to take place during permit issuance, permit renewal, or significant permit modification, the change management strategy ensures that adequate oversight by the public and EPA occurs. This determination and approval by the permitting authority must take place during a process in which EPA and the public are afforded the opportunity to review and comment on the

methodology and upon its initial use. The EPA requires that the streamlining process contained in its White Paper Number Two issued March 1996 be used to accomplish this review (including the submittal of the demonstration to EPA while a complete application containing the demonstration is otherwise submitted to the permitting authority). Application of the methodology and its outcomes must also be reflected in the OSIL. Verification of its use as well as the supporting calculations and analyses will be included (consistent with confidential business information protections) as part of the quarterly OSIL report describing changes since the last report. This report shall be submitted to the permitting authority on a quarterly basis and be made available to the public and EPA.

It should be noted that subpart GGG, while not specifying enough details to make some procedures replicable, typically does include guidance on what will be required. For example, the standard allows sources to demonstrate compliance for small control devices using a design evaluation and specifies for each type of control device the factors that must be included in this evaluation. This guidance facilitates the permitting authority’s review of the design evaluation that the source subsequently submits. Thus, in many cases, the standard provides the target for the design of a ROP, but leaves the details to be

proposed by the source and approved by the permitting authority.

While the mentioned ROPs should enable the vast majority of expected changes to be preapproved in the title V permit with respect to compliance with the MACT standard, some exceptions do exist. Changes governed by MACT provisions which are affected by any meaningful subjective judgments cannot be preapproved. This would include all procedures which are not replicable as contained in subpart GGG and are not otherwise approved during the permit issuance or revision process to be ROPs. In addition, certain requirements apply in a very event-specific fashion and cannot be preapproved without a precise advance understanding of a particular change. The EPA has already identified some requirements and procedures in the final MACT rule that cannot be relied upon or developed as ROPs, and thus may not be employed under the change management strategy.

For example, for any process unit complying with the pollution prevention alternative standard, an owner/operator must establish baseline production-indexed HAP consumption factors from which to apply the 75 percent consumption reduction requirement. Such baseline factors are determined from historical information, and the acceptability of the value depends on which historical years are selected to

represent the baseline and on the methods used for the involved material balance around the process unit. It is highly probable that each baseline consumption factor demonstration will encompass unique, process-specific information and methodologies that significantly affect the final value of the factor. With that in mind, the Agency feels that generic preapproval is not possible for changes whereby existing process units switch from complying with individual emission standards on emissions sources (such as a 93 percent reduction requirement for process vents) to complying with the pollution prevention alternative standard. It is appropriate that the permit revision process be used for making such changes.

An additional category not eligible for conversion to ROPs consists of determinations or approvals which have not been delegated to the permitting authority and must be submitted to EPA for approval. For example, the Administrator must review and approve, as appropriate, any source proposal for an alternative emissions limit or test method. Such reviews cannot therefore be addressed in advance by a ROP defined by the permitting authority.

The Agency has preliminarily reviewed the requirements of subpart GGG in the context of defining which of them contain: (1) ROPs as written; (2) requirements that can be established during the permit process as a ROP; and

(3) requirements which are ineligible for developing such procedures. Tables 3, 4, and 5 follow which describe this initial categorization. The EPA expects to address this subject more in its implementation guidance for subpart GGG.

TABLE 3. PROCEDURES THAT ARE REPLICABLE AS WRITTEN IN SUBPART GGG

Procedure	40 CFR Part 63 Citation
Calculating uncontrolled emissions from process vents--equations for eight types of operations	63.1257(d)(2)(i)(A) through (H)
Calculating controlled emissions from process vents discharged through a condenser--equations for eight types of operations	63.1257(d)(3)(i)(B)(1) through (8)
Equations for determining whether an existing vent is subject to 98% control	63.1254(a)(3)(i)
EPA performance test methods and calculations	63.1257(a)(2), (a)(3), (b)(1) through (8), and (b)(10)(i) through (iii)

TABLE 4. POTENTIALLY REPLICABLE OPERATING PROCEDURES THAT CAN BE ESTABLISHED THROUGH PERMITTING WHERE APPROVED BY PERMITTING AUTHORITY, AND SUBJECT TO REVIEW BY EPA AND THE PUBLIC)

Procedure	40 CFR Part 63 Citation
Evaluation of an air pollution control device capability for new scenario (not subject to testing).	63.1257(b)(8)(ii)
Establishing the emissions profile for inlet to control device	63.1257(a)(i)
Determining uncontrolled process vent emissions from an operation not covered by the eight equations in subpart GGG	63.1257(d)(2)(ii)
Determining whether a new/modified process vent is within the worst-case emissions approved for a control device	None
Determining annual HAP load in a wastewater stream	63.1257(e)(1)(iii)
Determining annual average HAP concentration in a wastewater stream	63.1257(e)(1)(ii)
Identification of wastewater streams that require control	63.1256(a)(1)
Evaluation of wastewater treatment unit capability for new scenario	63.1257(e)(2)(ii)
Demonstrating that wastewater tank emissions are increased no more than 5 percent by heating, treating with an exothermic reaction, or sparging	63.1256(b)(1)
Determining storage tank design capacity	63.1253(a)(1) and (2)
Maximum true vapor pressure for determining storage tank applicability	63.1251
Methodology for determining individual HAP partial pressures in nonstandard situations	63.1257(d)(2)(i)

TABLE 5. CASE-BY-CASE DETERMINATIONS REQUIRED

Procedure	40 CFR Part 63 Citation
Emissions averaging compliance alternative	63.1252(d)
Pollution prevention compliance alternative	63.1252(e)
Demonstrating that an equation in the rule is not appropriate in a specific case for an operation covered by one of the eight equations	63.1257(d)(2)(ii)
Demonstrating alternative test methods or emissions limits (or any other determinations which the Administrator has not delegated)	63.1261

The recommended approach for permits also assures that alternative operating scenarios are reasonably anticipated for the reconfigurations of permit-listed equipment by requiring the initial detailed linkages among processes, vents, PODs, tanks, control obligations, and eligible controls contained in the NOCSR to be incorporated into the permit. This incorporation of the baseline operation serves to define an important benchmark from which to anticipate similar, but different future operating scenarios using the same equipment.

The Agency believes that the more general description of equipment within each particular alternative operating scenario in the menu may be appropriate under the particular design of the pharmaceutical MACT standard. That is, a description of process equipment in less detail can be

justified here where the determination of process emissions is clear and a highly effective control approach is used, which is also versatile and effective enough to accommodate a wide range of inlet loadings (and the range is documented and specified on permits). Thus, a conservative approach to emissions reduction (e.g., most devices would operate as if the worst-case scenario were occurring), coupled with a replicable, objective basis (i.e., a required ROP for emissions calculation) to assure that each new change in operation is no more demanding on the control device than the previously established worst case, inherently allows more flexibility under which to “anticipate” a family of alternative operating scenarios.

One potential weakness of the change management strategy is that, before the mentioned ROPs can be relied upon to establish compliance obligations and to assure compliance with them, the strategy depends on the correct application of certain key definitions (e.g., process vent, process) and other regulatory provisions when a change in emissions occurs. Although EPA has carefully designed these definitions to be clear in their meaning, interpretive disputes could still conceivably arise. The Agency believes for several reasons, however, that there is an extremely low

probability for such disputes to occur and that the change management strategy should assure compliance with subpart GGG.

First, the industry, in its basic operations and how subpart GGG definitions will apply to them, is relatively well known. While this assertion may appear to run counter to previous statements regarding the constantly changing processes and equipment configurations that characterize much of the industry, in actuality, the process steps that make up the wide range of processes in the industry are confined to a relatively limited number of different chemical engineering unit operations. Thus, while the number of process steps, their order, and the specific conditions of each (e.g., temperature, solvents, etc.) may vary widely from process to process, the individual steps are basic, standard unit operations. The chemical engineering principles that govern these unit operations (and their air and wastewater emissions) are well understood. In addition, the FDA independently requires processes to be well defined which limits further any variations in definitional interpretations.

In addition to the significant protections that these inherent safeguards and the OSIL provide, the probability of misinterpreting the use of a particular definition is further reduced during the permit action that establishes

the change management strategy. As mentioned, the initial linkages among processes, vents, PODs, tanks, control obligations, and eligible controls contained in the NOCSR would be incorporated into the title V permit to establish the baseline scenario from which to envision future changes. This incorporation also serves to demonstrate an appropriate working knowledge with the key definitions governing the applicability of subpart GGG. More importantly, the permitting authority must specifically approve the source's use of these definitions and this approval is subject to review by EPA and the public. The result will be that the source and the permitting authority will have a well validated common understanding of how these definitions work and how to apply them to future changes.

The recommended approach also fulfills the need to provide adequate review opportunities. In the permit issuance process, the permitting authority, EPA, and the public all have an opportunity to review how the current source operations would comply with the standard and how the proposed permit conditions establish alternative operating scenarios to manage changes occurring with respect to this compliance baseline. In particular, these groups will have the opportunity to review the operating boundaries to assure equal or greater controllability of other emissions profiles and to determine any further need to add specific

operational constraints to safeguard against overloading the particular control device(s), for example, or additional permit terms or descriptions in order to assure compliance with the standard. The alternative operating scenarios as described in the permit must reasonably anticipate reconfigurations of existing emissions units and activities and the additions of certain other preapproved equipment and must contain the associated compliance obligations for these changes under subpart GGG, in order to afford permitting authorities, EPA and the public meaningful opportunity to ensure that the permit's alternative scenarios assure compliance with the MACT standard. To provide an ongoing opportunity to understand which alternative operating scenarios have been operated by the source and the specific corresponding compliance obligations that apply, the permit shall require quarterly transmission of the OSIL changes to the permitting authority, which shall make copies available to the public and EPA upon request.

The Agency is considering whether and to what extent the change management strategy for implementing subpart GGG might also be appropriate for other sources and applicable requirements. Preliminarily, EPA believes that the recommended permitting approach for subpart GGG will be essentially limited to the pharmaceutical and other similar batch chemical industries but it could be extended to

industries subject to other emission standards to the extent that EPA believes the same level of compliance assurance associated with the change management strategy described for subpart GGG would be achieved. The EPA expects to evaluate other situations individually, using the mentioned factors and other considerations as appropriate. Affected parties are encouraged to comment on the adequacy of other EPA rulemakings, (including those for other MACT standards) to address issues related to the change management strategy where similar needs for operational flexibility potentially exist. Certainly, the same legal constraints together with several situation specific factors (such as those involving the replicability of operating procedures contained in, or derived from, the applicable requirements, the potential for misapplication of the standard, the expectation for detailed descriptions and emissions reduction from the applicable requirement itself for subject equipment, and the ability of the control and monitoring approaches to accommodate changes) would again be relevant to defining whether a strategy for such applicable requirements based on alternative operating scenarios is possible under section 70.6(a)(9).

The EPA believes that the change management strategy should presumptively be limited to the pharmaceutical MACT, since other standards do not initially appear to produce

equivalent opportunities to create alternative operating scenarios under such a strategy. The most limiting element is the ability to predict accurately, using relatively simple, repeatable procedures, the effect a particular change has on emissions and compliance obligations. In the pharmaceutical industry, it is possible to do so in an extremely accurate fashion since HAP emissions nearly exclusively result from nonreactant solvent use. It may be more difficult, for example, to predict the effect of process changes in chemical manufacturing industries other than pharmaceutical manufacturing. Changes in these industries often involve complex reaction theory and reaction kinetics and other factors, which must be applied individually to the specific situation at hand to determine how HAP emissions will change. For most changes, it would be difficult to distill these chemical dynamics into an equation that would predict emissions variations for a source's process changes accurately. Without an accurate ROP, the applicable permit revision process would be necessary to reevaluate compliance under the change.

As previously mentioned, the Agency's decision whether to extend the availability of a change management strategy similar to that for subpart GGG to other standards will also depend on the empirical results achieved from implementing subpart GGG through such a strategy. In particular, EPA

expects to learn whether and how frequently interpretive disputes result from using the blend of definitions and approved ROPs relied upon to carry out the change management strategy and how to develop permit terms that establish and implement ROPs.

Finally, the Agency supports the testing of the recommended subpart GGG strategy since it is consistent with the Agency's program objectives to reinvent regulations, to eliminate delays and paperwork burdens, and to implement more efficiently the title V program. The development of the recommended approach benefited to a significant extent through the activities of a permitting pilot project which EPA initiated with the Environmental Quality Board of Puerto Rico and Merck Corporation. Considering the implementation of subpart GGG through title V permits in the context of this project has been extremely valuable in defining the type and frequency of anticipated operational changes and evaluating the appropriate permit content to assure compliance for these changes. The Agency is grateful to the participants in this Reinvention project and expects that its final results (in the form of more detailed guidance and/or model permit conditions) will be useful to others seeking to implement subpart GGG.

VII. Technical Amendment to 40 CFR Part 9

In compliance with the Paperwork Reduction Act (PRA), this technical correction amends the table that lists the Office of Management and Budget (OMB) control numbers issued under the RPA for this final rule.

The EPA is today amending the table in 40 CFR part 9 (Section 9.1) of currently approved information collection request (ICR) control numbers issued by OMB for various regulation. The affected regulations are codified at 40 CFR part 63 subpart GGG, sections 63.1259 and 63.1260 (recordkeeping and reporting requirements, respectively). The OMB control (tracking) number for this final rule is 2060-0358. The EPA will continue to present OMB control numbers in a consolidated table format to be codified in 40 CFR part 9 of the Agency's regulations, and in each CFR volume containing EPA regulations. The table lists the section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. The listing of the OMB control numbers and their subsequent codification in the CFR satisfy the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) and OMB's implementing regulations at 5 CFR part 1320.

This ICR was previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend

this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be necessary.

VIII. Administrative Requirements

A. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The principal purposes of the docket are:

1. To allow interested parties to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process; and

2. To serve as the record in case of judicial review (except for interagency review materials [section 307(d)(7)(A)]).

B. Executive Order 12866

Under Executive Order 12866, [58 FR 51735 (October 4, 1993)] the Agency must determine whether the regulatory action is “significant” and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines “significant regulatory action” as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of $100 million or more or adversely affect in a material way

the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, the OMB has notified the EPA that it considers this a “significant regulatory action” within the meaning of the Executive Order. The EPA submitted this action to the OMB for review. Changes made in response to suggestions or recommendations from the OMB were documented and included in the public record.

C. Enhancing the Intergovernmental Partnership Under Executive Order 12875

In compliance with Executive Order 12875, EPA has involved State governments in the development of this rule. These governments will be required to implement the rule. They will collect permit fees which will be used to offset the resource burden of implementing the rule. Representa-

tives of six State governments are members of the MACT partnership. This partnership group was consulted throughout the development of this final regulation. Comments from the partnership members were carefully considered. In addition, all States were encouraged to comment on the proposed rule during the public comment period, and the EPA fully considered all the comments submitted by States in this final rulemaking.

D. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq and has assigned OMB control No. 2060-0358. An information collection request (ICR) document has been prepared by EPA (ICR No. 1781.01), and a copy may be obtained from Sandy Farmer, Regulatory Information Division, U. S. Environmental Protection Agency (Mail Code 2137), 401 M Street SW., Washington, DC 20460, or by calling 202-260-2740.

The EPA is required under section 112(d) of the Clean Air Act to regulate emissions of HAPs listed in section 112(b). The requested information is needed as part of the overall compliance and enforcement program. The ICR requires that pharmaceuticals production facilities retain records of control device monitoring or HAP emissions

calculations records at facilities for a period of 5 years, which is consistent with the General Provisions to 40 CFR part 63 and the permit requirements under 40 CFR part 70. All sources subject to this rule will be required to obtain operating permits either through the State-approved permitting program or, if one does not exist, in accordance with the provisions of 40 CFR part 71, when promulgated.

The public reporting burden for this collection of information is estimated to average 4,800 hours per respondent for the first year and 2,600 hours per respondent for each of the second and third years. It is also estimated that there are approximately 100 facilities that are likely respondents. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying informa-tion, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and

requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15. The EPA is amending Table 9.1 in 40 CFR part 9 of currently approved ICR control numbers issued by OMB for various regulations to list the information requirements contained in this final rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) provides that, whenever an agency promulgates a final rule under 5 U.S.C. 553, after being required to publish a general notice of proposed rulemaking, an agency must prepare a final regulatory flexibility analysis unless the head of the agency certifies that the final rule will not have a signif-icant economic impact on a substantial number of small entities. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Agency certifies that this rule will not have a significant impact on a substantial number of small entities.

The EPA analyzed the potential impact of the rule on small entities and determined that only 16 of 56 pharmaceutical producing firms are small entities--not a substantial number of entities. Of these 16 firms, only 4 will experience an increase in costs as a result of the promulgation of today's rule that are greater than 1 percent of revenues. Therefore, the Agency did not prepare an initial regulatory flexibility analysis.

Although the statute does not require EPA to prepare an RFA because the Administrator has certified that the rule will not have a significant economic impact on a substantial number of small entities, EPA did undertake a limited assessment, to the extent it could, of possible outcomes and the economic effect of these on small pharmaceutical entities. That evaluation is available in the administrative record for today's action.

F. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with “Federal mandates” that may result in expenditures to State, local,

and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that the final standards do not include a Federal mandate that may result in estimated costs of, in the aggregate, $100 million or more to either State, local or Tribal governments, or to the private sector, nor do the standards significantly or uniquely impact small governments, because they contain no requirements that apply to such governments or impose obligations upon them. Therefore, the requirements of the Unfunded Mandates Act do not apply to this final rule.

G. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. § 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the congress and to the Comptroller General of the United States. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comproller General of the United States prior to publication of the rule in the Federal Register. This rule is not a "major rule" as defined by 5 U.S.C. § 804(2).

H. National Technology Transfer and Advancement Act (NTTAA)

Under section 12(d) of the National Technology Transfer and Advancement Act (“NTTAA)”), the Agency is required to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. Where available and potentially applicable voluntary consensus standards are not used by EPA, the Act requires the Agency to provide Congress, through the Office of Management and Budget, an explanation of the reasons for not using such standards.

The Agency does not believe that this Notice addresses any technical standards subject to the NTTAA.

I. Executive Order 13045

The Executive Order 13045 applies to any rule that EPA determines (1) “economically significant” as defined under Executive Order 12866, and (2) the environmental health or safety risk addressed by the rule has a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children; and

explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This final rule is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because it does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

LIST OF SUBJECTS

40 CFR PART 9

Environmental projection, Reporting and recordkeeping requirements.

40 CFR Part 63

Air pollution control, Hazardous substances, Incorporation by reference, Reporting and recordkeeping requirements.

Dated:

Carol M. Browner,
Administrator